IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

HUDSON SURGICAL DESIGN, INC.,	)	
	)	
Plaintiff,	)	Civil Action No. 08 C 1566
	)	
v.	)	Judge Virginia M. Kendall
	)	Magistrate Judge Nan R. Nolan
ZIMMER HOLDINGS, INC., ZIMMER, INC., RUSH SYSTEM FOR HEALTH, and RUSH UNIVERSITY MEDICAL CENTER,	)	
	)	
Defendants.	)	

RUSH UNIVERSITY MEDICAL CENTER'S
OPPOSITION TO HUDSON'S MOTION TO COMPEL

Rush University Medical Center ("Rush Medical") is a major metropolitan area general service teaching hospital which provides, among its other services, the community with a place where state licensed physicians can perform knee replacement surgeries. Rush Medical approves state-licensed physicians to practice at its hospital, giving them staff privileges to perform general procedures such as knee replacement surgery (total knee arthroplasty or "TKA"). Rush Medical does not employ the surgeons to do the surgery or control the surgeons as they perform the surgery. The surgeons are employed by non-related entities such as physician's groups. The entire arrangement is similar to the relationship this District Court has with the lawyers to whom it has provided admission to its trial bar. The District Court admits state-licensed lawyers with the required experience to the District Court trial bar and allows them to perform certain actions before the Court. The Court does not employ the lawyers; like the surgeons the lawyers are independent contractors allowed to use this Court's courtroom facilities for trials.

Rush Medical provides a sterilized surgical theatre, some basic equipment, support staff, and the surgical instruments specifically requested by the independent physician for each surgery. Rush Medical does not conduct the surgery or use devices in the surgery – that is the

role of the independent physician. Again, this is analogous to a District Court, which provides a courtroom, support staff and other items, but does not control the independent methods or techniques of the attorneys who try a case.

Hudson's discovery demands and its infringement contentions generally are based on Hudson's erroneous assumption, based on some web pages, that there are "Rush Medical physicians," who Rush Medical allegedly controls and orders to use particular devices and surgical techniques that infringe Hudson's patents. That is simply not the case, and is similar to asserting that the District Court should be liable for the actions of lawyers who are admitted to the trial bar in this District and advertise that admission on their websites. Rush Medical does not employ the surgeons, does not utilize medical devices, and does not perform surgeries. Rush Medical has repeatedly advised Hudson of these facts and, as established below, provided the documents that prove it. Still, Hudson continues its onerous demands. All of Hudson's discovery requests can be denied based on this reason alone.

Hudson brought this action for patent infringement based on two patents. The first patent, U.S. Patent No. 5,643,272 ("the '272 patent"), issued in 1997. This is the only patent that issued before 2008, and so it is the only possible basis for Hudson's pursuit of discovery prior to that date. The asserted claims of the '272 patent are for an *apparatus* only; there is no allegation of any infringing *surgery* or *implant* based on this patent. Hudson's claim to entitlement to all documents relating to certain surgeries or implants[1] from 2002 through March 2008 based on this patent are completely without merit. Further, the device claimed in the '272 patent is very limited and relates only to an apparatus for cutting the *tibia*. '272 Patent, claim 8 ("An apparatus for resecting a proximal human tibia comprising ..."). The scope of the claims is not even

[1] Defined by Hudson as the "Accused Techniques" and "Accused Implants", respectively.

arguably related to the Minimally Invasive Quad-Sparing Technique, which by its terms (i.e. quad, which is short for quadriceps, a muscle in the *upper* leg) focuses more on the femur (the thigh bone) than the tibia (a bone in the lower leg). Hudson is not entitled to discovery from 2002 through March 2008 on "Accused Instruments," which is defined by Hudson as instruments used in Quad-Sparing surgeries, because the '272 patent is not directed to Quad-Sparing surgeries.

As detailed below, it is clear that neither Rush Medical nor physicians with privileges at Rush Medical infringe the '272 patent because there are several elements of the patent not present in devices used at Rush Medical, and so it cannot serve as a basis for extensive discovery covering a six-year period that would greatly burden medical staff at the hospital. Non-infringement can be seen just by looking at the parts and apparatus, and in no way requires the tremendous amounts of discovery which Hudson now seeks.

Hudson's requests for additional documents and information are based on the faulty premise that a patent on an apparatus entitles its holder to discovery on each and every use of that apparatus. That is simply not the case. For example, if you have a patent on a power drill, you are entitled to discovery on whether an alleged infringer possesses a power drill that infringes your patent. You are not entitled to discovery on the thousands of occasions in which the accused infringer uses the drill to build something. Similarly, a patentee with an apparatus claim on a drill may be entitled, if infringement is proven, to a reasonable royalty based on the profits on the sale of that power drill. The patentee is not entitled to profits relating to every use of that drill. Discovery regarding the construction or value of every house built with the drill would be unnecessary, unduly burdensome, and irrelevant to any infringement or damage analysis, just like Hudson's requests in this case.

Rush Medical and/or co-Defendant Zimmer Inc. have already produced documents that are sufficient to show whether the '272 patent's apparatus claims are infringed, including: (1) diagrams of the tibia device; (2) pictures and videos of the device as delivered to the operating room and in use; (3) all tracking history data for the device from operating room to sterilization which is available on Rush Medical's current system; (4) the number of knee implants used over the last six years; and (5) a sample of a physician's operating notes which show that the notes do not provide information on the issue of infringement of the '272 patent. Rush Medical has also agreed to allow Hudson to inspect its sterilization area where the allegedly infringing devices are held and sterilized before surgeries. Taken together, these documents and information are more than sufficient to resolve the infringement issue.

Hudson now pushes for unlimited discovery on each and every quad-sparing knee replacement surgery since 2002, even though the '272 patent is not directed at quad-sparing surgeries and the other patent asserted issued in 2008. This discovery is not reasonable. The number of surgeries is great; it is estimated that well over 5,000 surgeries have been performed at Rush Medical in this time frame. To produce all the information from each surgery would be a tremendous burden to a working hospital – each separate surgery would have to be called up and the documents tracked down for each. Further, the information held by Rush Medical is highly sensitive. Federal Regulations under HIPAA *mandate* strict maintenance of patient confidentiality to protect personal medical information. In practice, this would require Rush Medical's attorneys to spend literally hundreds of hours reviewing and redacting private patient information before anything could be produced.[2] Finally, as shown by the sample Rush Medical

[2] Hudson has repeatedly attempted to dismiss Rush Medical's concerns about patient privacy simply because a protective order is in place in this case. This demonstrates a serious misunderstanding of the federal regulations governing disclosure of private medical information.

produced, the surgery notes do not provide information as to how the devices used in surgery were constructed, which is what is at issue with respect to alleged infringement of the '272 patent's apparatus claims. The cost to Rush Medical would be for naught. Rush Medical therefore requests that this Court deny Hudson's motion to compel as to documents and information from 2002 until March, 2008.

Hudson is also asserting that Rush Medical is responsible for certain accused *methods* (no apparatus claim is asserted for this patent) for U.S. Patent No. 7,344,541 ("the '541 patent"). First, the '541 patent issued on March 18, 2008. It can not be the basis for allegations of infringement or discovery before March 18, 2008.

Second, as explained above, it is the physicians, not Rush Medical, who perform the allegedly infringing knee replacement surgeries. Rush Medical has repeatedly, starting months ago, advised Hudson of this fact and that it would be prudent for Hudson to seek discovery from these non-employed physicians, who are the only ones who know what techniques and tools were used in surgery, before burdening a working hospital. This is feasible because fact discovery does not end until February, 2009, giving Hudson plenty of time. Hudson has not initiated any such discovery.

Third, discovery on Rush Medical would impose an undue burden because of the attorney time required to satisfy HIPAA, especially in light of the fact that the Physician's Notes Rush Medical produced as a sample do not provide enough detail to determine whether there is infringement of the method claims of the '541 patent.

Finally, Hudson's motion to compel is premature.[3] While this case was initiated in March, substantive discovery from both sides has only recently begun. Indeed, Hudson, the plaintiff in this action, did not serve its initial contentions of infringement until July 9, 2008. As of August 6, 2008, the date on which Hudson filed its motion to compel Rush Medical to produce *additional* internal documents, Hudson had failed to produce a *single* internal document. Fact discovery does not close for another six months, on February 27, 2009. Further, Hudson has not conducted the required meet and confer requirement of this Court, which requires a telephone conference before filing a motion to compel. Local Rule 37.2.[4] As a result, Hudson's demands have not been sufficiently focused as to specific documents or information, leaving the Court with Hudson's request for general enforcement of broad, vague, and indefinite discovery requests. Hudson's motion should be denied for failure to meet and confer.

[3] Rush Medical is not going to drag the Court through each correspondence and telephone conference on these issues, but refers the Court to its July 25, 2008 letter that provided responses to many of Hudson's requests. (Ex. J). Hudson did not respond to that letter with a phone call or letter regarding the discovery it now seeks before filing this motion.

[4] LR37.2. Motion for Discovery and Production:

> To curtail undue delay and expense in the administration of justice, this court shall herafter refuse to hear any and all motions for discovery and production of documents under Rules 26 through 37 of the Federal Rules of Civil Procedures, unless the motion includes a statement (1) that after consultation in person or by telephone and good faith attempts to resolve differences they are unable to reach an accord, or (2) counsel's attempts to engage in such consultation where unsuccessful due to no fault of counsel's. Where the consultation occurred, this statement shall recite, in addition, the date, time and place of such conference, and the names of all parties participating therein. Where counsel was unsuccessful in engaging in such consultation, the statement shall recite the efforts made by counsel to engage in consultation.

1. Hudson has not shown that it is entitled to additional discovery from Rush Medical before March, 2008, and cannot because there is clearly not infringement of the 1997 patent.

In addition to the reasons outlined above, Hudson is not entitled to any additional discovery from Rush Medical for before March 18, 2008 because there is no question that the '272 patent is not infringed. The '272 patent, which issued in 1997, is the only reed upon which Hudson can seek pre-March 2008 documents and information. Contrary to Hudson's discovery demands, which relate to quad-sparing total knee replacements, the '272 patent is only for a specific apparatus for cutting a tibia. '272 Patent (Ex. A). Hudson has asserted one independent claim of the '272 patent, and it reads:

> *An apparatus* for resecting a proximal human tibia comprising:
>
> alignment means having proximal and distal ends;
>
> distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;
>
> fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;
>
> cutting guide means interconnected with the alignment means, the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia, the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and
>
> milling means for cutting the tibia, the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

Id, at claim 8 (emphasis added). To infringe a patent, an accused device must have every element of the asserted claim; if the accused device is missing even one element, there is no patent infringement. *Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005) (for "infringe[ment] of an apparatus claim, the device must meet all of the structural limitations").

In this case, there is no reasonable question that the '272 patent is not infringed by Rush Medical. This is likely the reason Hudson did not initiate this suit until the '541 patent issued in March 2008, eleven (11) years after the '272 patent issued in 1997. Rush Medical does not infringe the '272 patent for at least three reasons. First, Rush Medical does not provide an apparatus that is fully assembled, which is required by Claim 8's repeated element of "interconnected." Second, the apparatus used at Rush Medical does not have two or more cutting guides that are placed on opposing sides of the tibia, which is also required in Claim 8. Third, Rush Medical does not use the alleged infringing device.

First.[5] Rush Medical does not infringe Claim 8 because it provides, at most, unassembled, different components in a tray to a doctor performing a surgery, which are not "interconnected." *See* RUMC0001933 (instruments from Tibial Cutting Tray laid out for a picture) (Ex. B). A recent Federal Circuit decision, which is controlling authority for this patent infringement case, confirms that providing separate components cannot constitute direct infringement of a claim that requires a connection. *Cross Medical*, 424 F.3d 1293. In *Cross Medical*, like in this case, the patent claim in question was for a medical device. The claim there required a "lower bone interface operatively joined to said bone segment." The Federal Circuit held that the term "joined" meant that "the interface and the bone must be brought together or connected to form a single unit." In the instant case, the similar claim language requiring the different components to be "interconnected" must mean that the different components actually be connected together.

In *Cross Medical*, there was a question as to whether surgeons would later connect the interface and the bone. The Federal Circuit held that inquiry completely irrelevant on the

[5] For a more detailed showing of how Claim 8 is not infringed, please see Rush Medical's First Supplemental Response to Hudson's First Set of Interrogatories. (Ex. F).

question of direct infringement, "Because Medtronic does not itself make an apparatus with the 'interface' portion in contact with bone, Medtronic does not directly infringe." *Id.* In *Cross Medical*, the patentee argued that there could be direct infringement because the device supplied by Medtronic was *capable* of being connected. The Federal Circuit rejected that argument because "the claim does not require that the interface be merely 'capable' of contacting bone; the claim has a structural limitation that the anchor seat be in contact with bone." Because for "infringe[ment] of an apparatus claim, the device must meet all of the structural limitations," the Federal Circuit held there was no direct infringement. *Id.* ("Cross Medical again fails to recognize that the limitation ... is absent until the screw and anchor are put in place during surgery.")

Similarly, in this case, Claim 8 includes the structural limitations that the different components be "interconnected." Claim 8 is limited to actual "interconnection;" there is nothing in the claim to suggest that being "merely capable" of interconnection is sufficient.

At Rush Medical, a physician preparing for surgery must request that certain components be provided at a given surgery on a Preference Card. *See* RUMC0001543-1545 (EX. C). The components in question are provided in separate pieces on a surgical tray that is called the "MIS Tibial Cutting Jigs." The list of items found on that tray is set ahead of time. *See* RUMC0001565 (Ex. D). Rush Medical has produced a picture of the items found on the tray. RUMC0001933 (Ex. B). The MIS Tibial Cutting Jigs are provided for surgery in component parts that are not connected together. The physician during surgery is in charge of assembling the components how he/she sees fit for the particular surgery. Rush Medical has no input into that decision. Furthermore, Rush Medical does not own the MIS Tibial Cutting Jigs. Rather, they are simply stored at Rush Medical on consignment. Because Claim 8 requires

interconnected parts, not separate components, possessing or providing a surgical tray with unconnected components cannot directly infringe Claim 8 of the '272 patent.

Dependent Claims 9-10 are similarly not infringed. *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1553 n.9 (Fed. Cir. 1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to infringe.").

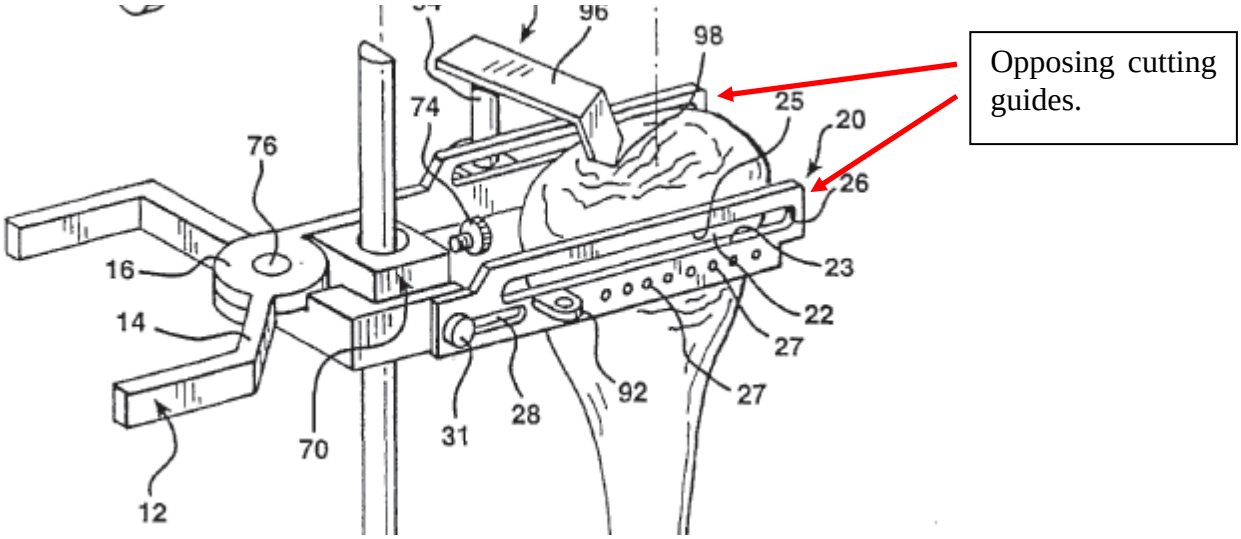
Further, Rush Medical cannot be found liable for indirect infringement before March, 2008, because, Rush Medical was not aware of the '272 patent before initiation of this lawsuit. Awareness of the patent is required for indirect infringement. Hudson admits that it did not provide notice of the patents-in-suit to Rush before March 18, 2008. *Hudson's Resp. to Rush Medical's Interrogs., at 13* (Ex. E). Rush Medical had no knowledge of the patents-in-suit before Hudson filed this suit. *Rush Medical's Supp. Resp. to Hudson's Interrogs., at 29-30* (Ex. F). Hudson's only support for its contention that Rush Medical was aware of the '272 patent before this lawsuit is a vague allegation regarding the knowledge of Drs. Berger and Rosenberg, who are not agents or employees of Rush Medical. *Hudson's Resp. to Rush Medical's Interrogs., at 13* (Ex. E). Even if Drs. Berger or Rosenberg were aware of the '272 patent, their knowledge cannot be imputed to Rush Medical. Because Rush Medical had no knowledge of the '272 patent before this lawsuit, it cannot be held liable for indirect infringement.

Second. Independently, no surgery performed at Rush Medical has been shown to have multiple cutting guides interconnected with the rest of the apparatus that are positioned on opposing sides of the tibia, which is required by Claim 8 of the '272 patent:

> cutting guides positionable in opposing relation along sides of the tibia, the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia

'272 Patent, at Claim 8 (Ex. A) (emphasis added).

FIGURE 6 of the '272 Patent



As is clearly shown in the figure, the opposing cutting guides are on opposite sides of the tibia and clamp around the tibia. Further, the fact that cutting guides according to the '272 patent were opposing was **critical** to patentability. As described more fully in Rush Medical's Supplemental Interrogatory Response (Ex. F), the opposing cutting guides were added by amendment to avoid the prior art and were required by the Patent and Trademark Office before it would allow the patent issue.

Videos of surgery conducted by a physician at a Rush Medical facility have been produced, and they were performed by Dr. Berger.[6] However, Dr. Berger does not employ opposed cutting guides. Here is a picture of the only device used in those surgeries:

[6] Videos would be hard to produce in connection with this opposition, but *Hudson's* claim charts, as explained below, show that only one device is actually used in the surgery. Rush Medical is willing to furnish the Court with a copy of the video at the Court's request.

This device is attached to only one side of the tibia during the surgery. There is therefore no infringement of claim 8 of the '272 patent.

The non-infringement of claim 8 is further confirmed by Hudson's claim charts. Those claim charts conspicuously show that there are not cutting guides in opposing relation used during knee replacement surgeries. The charts include actual pictures of the tibial cutting apparatus that do not have such opposing guides. Indeed, the claim charts include a legend that states that such parts are "not shown." *Hudson's Prelim. Claim Chart at 19, 21, 23* (Ex. G). These parts are not shown because they are not actually utilized. Because it is axiomatic that an accused apparatus must have all of the elements of a claim, and Hudson's own claim chart shows that the devices in question do not have all the elements, a finding of non-infringement is mandated.

2. The physicians who perform surgeries at Rush Medical are not employees or independent contractors of Rush Medical and are not under Rush Medical's control; Hudson's discovery requests on the actual surgeries, which are performed by the physicians, should be addressed to those physicians and not to Rush Medical.

Rush Medical is a medical hospital that makes available operating rooms and related operative services to physicians who have applied for and received approval for clinical privileges at Rush Medical. Rush Medical does not employ the surgeons who perform knee replacement surgeries at Rush Medical. These doctors are independent of Rush Medical. They are not employees for purposes of conducting surgeries, but have merely applied for clinical privileges to engage in knee replacement surgeries. The clinical privileges granted by Rush Medical are general and, in the context of this litigation, do specifically reference or authorize surgical techniques like Hudson's Accused Techniques. For example, Rush Medical approved Dr. Berger's application for clinical privileges related to orthopedic surgery. RUMC0001991-2015 (Ex. H). Dr. Berger was (and is) approved for "Core Privileges" of the knee. RUMC0001991 (Ex. H). Dr. Berger is also approved for "[u]se of external fixator device in leg and knee" and "[a]rthroplasty of the knee." RUMC0002000 (Ex. H). As can be seen from the clinical privileges for Dr. Berger, Rush Medical's approvals are broad based and do not concern the specific implants, devices, or techniques that Dr. Berger chooses to utilize in his surgeries.

Rush Medical does not actually perform the surgeries; the individual physicians with staff privileges at Rush Medical perform them. Rush Medical makes its operating rooms available to physicians who have staff privileges. The physician can reserve an operating room for a certain time period. Rush Medical has a "Preference Card" system. Rush Medical produced a sample Preference Card for Dr. Berger. RUMC0001543-1545 (Ex. C). The Preference Card lists the instruments, equipment and supplies that the physician requests be present in the operating room

for a surgery. *Id.* Rush Medical does not choose the instruments, equipment and supplies to be used; rather, the physician makes that choice through his/her Preference Card.

As can be seen from Dr. Berger's Preference Card, the procedure performed during that surgery was an "Arthoplasty Total Knee." For that procedure, Dr. Berger requested, inter alia, the "MIS Tibial Cutting Jigs," which are detailed above. Those Jigs, and the other tray components, can be assembled and used in non-infringing manners. Rush Medical simply provides component parts as requested by the physician through the Preference Card. Rush Medical does not tell the surgeon which components to use, how to use or construct any apparatus (and thus has no involvement vis-a-vis the '272 patent), or how to conduct his or her surgery (and thus has no involvement vis-a-vis the '541 patent).

Rush Medical's website very clearly explains that many of the doctors on the medical faculty of Rush Medical are in private practice and are, therefore, not the agents or employees of Rush Medical. *RUMC0005010-5011* (Ex. I). The documents produced by Hudson as of the filing of this motion show no indication that Hudson ever bothered to investigate whether their doctors of interest were actually employees or agents of Rush Medical. In fact, because the doctors that Hudson specified to Rush Medical were originally identified by Hudson from the Midwest Orthopaedics website, (*See Hudson Motion to Compel*, at 7), Hudson was on notice that these doctors are independent practitioners who are neither agents nor employees of Rush Medical. This makes Hudson's resistance to seeking production from the doctors themselves all the more puzzling.

In sum, the physicians operate independently of Rush Medical and so Rush Medical cannot be held liable for their independent acts while in the operating theatre. Rush Medical has repeatedly advised Hudson that the physicians are independent of the hospital (and only have

staff privileges similar to being admitted to practice in a Court), and that Hudson should seek discovery on them because they have personal knowledge. Hudson should seek discovery from the best source for its desired information – the doctors themselves – before subjecting Rush Medical to what may be unnecessary, duplicative, or even futile discovery requests.

3. Hudson is not entitled to the broad discovery it is now seeking.

Hudson is seeking broad discovery concerning "all" documents or persons with "any involvement" relating to a wide area of activities relating to all implants, techniques, and instruments for quad-sparing surgery. Most of Hudson's requests also cover a wide range of dates extending back to 2002, but are not specifically limited to items relating to the '272 patent, which is the only patent that goes back that far.

Additionally, Rush Medical does not categorize its documents according to the definitions provided by Hudson. It is therefore difficult, if not impossible, to track down documents that may or may not be responsive. Finally, if read literally, Hudson's document requests would likely cover tens of thousands of documents, many of which would include private patient information protected by HIPAA. It would be an undue burden for Rush Medical to be ordered to produce documents responsive to these requests as worded.

The parties have been talking about certain ways to limit the discovery responses, and Rush Medical has continued to produce additional documents and information, as it said it would do in correspondence and responses provided to Hudson before it filed its motion to compel. Indeed, Rush Medical produced supplemental interrogatory responses on Friday, August 15, 2008 and additional documents on Monday, August 18, 2008.

It is quite common in discovery for a party to serve broad requests that literally encompass many, many documents, and then boil them down through discussion and rolling

discovery to focus on specific types of documents that a party actually requires. That process has not been completed in this action. Hudson's motion is premature because there was no meet and confer, and its request that the Court order Rush Medical to provide all potentially responsive documents is simply untenable because as Hudson's requests are worded, such an order would literally encompass most every document Rush Medical has in relation to knee replacement surgeries over the last six (6) plus years. Because Hudson has not sought specific documents, its motion to compel should be denied.

4. Specific Responses to the Discovery Requests of Hudson.

Below, Rush Medical provides specific responses to each of Hudson's discovery demands, grouping the discovery in the same way Hudson does in its motion to compel. Hudson's requests are premature because Rush Medical has produced and continues to produce documents, and so it is difficult to determine which of Hudson's arguments still apply. Rush Medical asserts, however, that the individual responses are not necessary because Hudson's motion should be denied outright based on the arguments raised above.

Interrogatory No. 1

This Interrogatory, like the others, is overbroad. It is not temporally limited. Further, it seeks pre-March 2008 information on Accused (Quad-Sparing) Techniques, Instruments and Implants even though the '272 patent only applies to an apparatus for tibial resection. Hudson has made no showing that anyone employed with Rush Medical was marketing a tibial resection apparatus at any time.

Even though the Interrogatory is not proper, Rush supplemented its 26(a)(1) disclosure with much of the information sought in Interrogatory No. 1. That information, while not discussed by Hudson in its motion to compel, was provided on July 11, 2008, before Hudson

filed that motion. Rush Medical further supplemented its interrogatory response, as it said it would before Hudson filed its motion, with additional information on August 15, 2008. Rush Medical's Supplemental Interrogatory Response is sufficient. At the least, any decision on this Interrogatory would be premature because the parties have not discussed what additional material Hudson is seeking or focused the issue for the Court.

Interrogatories Nos. 2 and 3

Interrogatory No. 2 is overbroad and would unduly burden Rush Medical. In effect, it is six different interrogatories in one, because it seeks six different subsets of information for every surgery, including the number, the date, the location, the physician, the gross revenue, the gross profit, the operating profit, the incremental profit, the number of implants, the total revenue per implant, the gross profit per implant, the operating profit per implant and the incremental profit per implant. It would require review of each and every knee replacement surgery (estimated at well over 5,000). Further, all of the requested information (to the extent it exists) for each surgery would not be located in one area, but in disparate areas, requiring multiple searches of information for each surgery. Even if found, much of this information is protected by HIPAA and would require substantial, case-by-case review by Rush Medical attorneys to ensure that private medical information is not disclosed.

Hudson is not entitled to such broad discovery. The '272 patent, which is the only basis for discovery pre-March 2008 is limited to an apparatus that is a small part of knee replacement surgeries. The '272 patent's apparatus claim (analogous to one for a power drill) does not entitle Hudson to broad discovery on uses of that apparatus (all quad-sparing techniques) or other devices (accused implants) that are not claimed in any Hudson patent.

For Interrogatory No. 3, which is limited to Accused Instruments, Rush Medical supplemented its response to identify documents that provide information relating to a tibial cutting device used by some physicians at the Rush Medical facility, which Rush Medical agreed to do before Hudson filed this motion to compel. At the least, any decision on this Interrogatory would be premature because the parties have not discussed what additional material Hudson is seeking or focused the issue for the Court.

Interrogatory No. 4

This Interrogatory seeks information relating to Quad-Sparing Surgeries, Knee Implants, and Surgical Devices used in Quad-Sparing Surgeries. For pre-March 2008, because the '272 patent is limited to a tibial resection apparatus, Hudson is not entitled to discovery on surgeries or implants. Rush Medical has explained to Hudson that it does not receive and/or make payments that are based on the tibial cutting device used at Rush Medical, which is not owned by Rush Medical but is on consignment.

As to post-March 2008 information, Rush Medical has explained that it does not base its charge for operating room time on the specific technique used by the surgeon in the operating room. Rush Medical has provided information relating to the use of implants even though the implants are not covered by any patent of Hudson. Rush Medical has also agreed to supplement this interrogatory as discovery proceeds. Hudson's motion to compel related to this interrogatory should be denied.

Interrogatories Nos. 5-7

Rush Medical acknowledges that it should provide its positions on invalidity and non-infringement, and stated in its response that it was investigating its responses. Rush Medical was sued without warning by Hudson in March, 2008 and had no notice before then that Hudson was

bringing this action. Needless to say, Rush Medical had not formulated any non-infringement or invalidity contentions at that time.

Further, Rush Medical did not receive Hudson's infringement contentions until July 9, 2008. Those infringement charts are over five-hundred (500) pages long. Before receiving that chart, it was not possible to determine exactly what Hudson alleged its patent covered, which is a prerequisite to both infringement (comparing the patent to the accused device) and invalidity (comparing the patent to the prior art). Additionally, Rush Medical does not control the surgeries at Rush Medical, it only provides an operating theatre and the materials requested by the surgeons. It may be difficult for Rush Medical to provide non-infringement contentions when each surgeon performs different techniques in the operating room at the level of specificity required to respond. Rush Medical has repeatedly advised Hudson that it should seek discovery from the surgeons so that the exact methods used during surgery can be ascertained and analyzed.

Rush Medical also has to analyze the file histories of the patents-in-suit to finalize its contentions. For the '541 patent, which Hudson claims to have been prosecuting through a long continuation chain for over 12 years at the Patent and Trademark Office, this analysis will be extensive.

Rush Medical has updated its Interrogatory response regarding non-infringement for the '272 patent, which is an apparatus claim that can be more easily analyzed. Fact discovery lasts until February, 2009. Rush Medical plans on continuing to supplement its responses in a timely manner as this case proceeds.

Interrogatory No. 10

This discovery request goes to damages. Neither party has engaged in substantial discovery on damages to date. Indeed, as of the filing of its motion to compel, Hudson had not produced a single internal document. Further, Hudson did not respond to Rush Medical's interrogatories with the information it is now seeking from Rush Medical, instead identifying factors to be considered without providing a response and stating that it would be relying on an expert.

Given the nascent stage of discovery on damages at this point and the fact that there is a high probability that there is no infringement of the '272 patent, which is the only patent that extends before March, 2008, it is prudent to discuss bifurcating the issue of damages. Bifurcation is often used in patent cases because they are complex and costly (requiring experts on both sides), and bifurcation is especially used where there is a reasonable probability that damages discovery would be mooted by a finding of non-infringement. Here, a finding of no infringement of the '272 patent would limit the damages inquiry to March, 2008 and after. Rush Medical intends to discuss with Hudson whether bifurcation might be appropriate in this case. The Court should not compel Rush Medical to respond to this interrogatory, especially at this time.

Interrogatory No. 12

Rush Medical has supplemented its response to this Interrogatory. Rush Medical thinks that the issues surrounding this interrogatory should be resolvable between the parties without Court intervention. This again highlights the premature nature of Hudson's motion to compel.

Interrogatories Nos. 13, 14

Rush Medical has answered these interrogatories and will continue to supplement its responses should its investigation reveal any additional documents. Fact discovery does not end

until February, 2009. Rush Medical has stated that it has identified all documents revealed to date. There is not much more it can do at this point of the litigation, and Hudson's request is inappropriate at this time.

Document Requests

For the reasons stated above, Hudson is not entitled to documents relating to Accused Techniques or Accused Implants prior to March, 2008 because the '272 patent is limited to an apparatus. Rush Medical has endeavored to produce documents relating to tibial cutting devices used at Rush Medical, and will continue to do so. Rush Medical responds to each class of documents identified by Hudson.

However, it should be noted that Hudson's actual discovery requests are much broader than the documents it specifically identifies in its motion. Even if this Court were inclined to compel any discovery, it should limit its order to specific types of documents mentioned in the motion to compel.

A. Documents relating to the surgeons.

It is telling that Hudson went to, inter alia, the Midwest Orthopaedics website to determine the doctors who have privileges at Rush Medical to perform knee replacement surgeries. Hudson's Motion to Compel 7. That is because, on information and belief, it is Midwest Orthopaedics that actually employs the doctors, **not** Rush Medical. Rush Medical has repeatedly advised Hudson that it should seek discovery from Midwest Orthopaedics and/or the doctors themselves.

Rush Medical agreed to supplement its production before Hudson filed its motion to compel without a meet and confer conference. Rush Medical has been able to pull all Preference

Cards that reference the MIS trays, and has produced those documents. Hudson now knows which doctors use these trays.

B. The Specifics of the Surgeries

Hudson is not entitled to the specifics of the surgeries for before March, 2008 because the '272 Patent is limited to an apparatus claim, not a surgery. Further, every video of a surgery or portion of a surgery produced to date by Hudson and/or Zimmer clearly shows that the '272 patent is not infringed because of the reasons stated above. Additionally, Rush Medical provided a sample surgeon's notes from a quad-sparing surgery. Those notes did not have the specificity that would be necessary to determine whether an infringement occurred. Only the doctor, who performs the surgery, knows precisely what happens. Rush Medical has advised Hudson of this fact on many occasions and suggested that Hudson seek discovery from the doctors, but Hudson has refused.

Rush Medical does not perform a surgery. Rush Medical provides a surgical room and some equipment that is specifically requested by the doctor. It cannot be liable for infringement, and it is untenably burdensome to require production of all documents when Rush Medical cannot be implicated.

Additionally, there are literally thousands of surgeries covered by Hudson's document requests. It would take hundreds of hours to locate all of these documents and to redact them to protect patient confidentiality to meet the requirements of HIPAA. This would be an undue burden in light of the fact, as established in the sample card, that the surgeon's notes are not determinative of infringement.

If the Court determines that this extensive discovery is warranted but for consideration of the undue burden placed on Rush Medical, then fee shifting should be employed. If Hudson

really thinks these documents are worth the effort, Hudson can pay for their retrieval by reimbursing Rush Medical for the cost of obtaining the surgical reports. The costs would include overtime costs to have a person at Rush Medical specifically tasked to locate these thousands of documents and the legal fees necessary for Rush Medical and its counsel to properly redact these materials to satisfy HIPAA.

C. Quad-Sparing Instruments

Rush Medical has produced the documents showing its chain-of-custody for the accused instruments that are available on its current software system, which extends back into 2007. This information is more than enough for this litigation because the '272 patent is an apparatus patent. Hudson is not entitled to damages for the use of the apparatus by physicians, and so there is no need to examine every knee replacement surgery from the last six years to determine which of them used the tool in question. Rush Medical should not be forced (if it is even possible) to track down information stored on discontinued computer systems, especially since Hudson has had the '272 patent since 1997 and chose to wait 11 years before initiating this suit. Any difficulty in retrieving documents from before the initiation of this suit was caused by Hudson's delay in bringing this action. To the extent it is ordered (and it should not be), attempts to retrieve documents from older, discontinued systems should be paid for by Hudson.

The number of implants used is not relevant because Hudson does not have a patent that is directed to an implant. In the spirit of cooperation, Rush Medical produced information on the implants used in surgeries performed at Rush since 2002. But every time Rush Medical produces documents, Hudson just seeks more with no end in sight. This Court should deny any request to produce additional information on implants because they are not relevant to a patent claim at issue here.

Rush Medical timely responded to Hudson's request to inspect the instruments it holds at its facilities and agreed to permit an inspection. This is another example of Hudson's motion to compel being premature. Rush Medical is allowing Hudson to come into its sterilization facility where the instruments are stored to videotape and photograph these instruments. Hudson will be able to see all of the instruments that are in Rush Medical's possession at that time, so this subject matter is moot.

CONCLUSION

For the foregoing reasons, this Court should DENY Hudson's motion to compel.

Dated: August 18, 2008

Respectfully Submitted,

By: /s/ Brian J. Sodikoff
One of the Attorneys for Rush System for Health and Rush University Medical Center.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document, along with the non-confidential exhibits, was served on the following via the Court's ECF system. Further, a confidential version including all exhibits was served via hand delivery:

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EXHIBIT A

US005643272A

United States Patent [19]

Haines et al.

[11] Patent Number: 5,643,272

[45] Date of Patent: Jul. 1, 1997

[54] **METHOD AND APPARATUS FOR TIBIAL RESECTION**

[75] Inventors: **Timothy G. Haines**, Stewartsville; **David B. Goldstein**, Weehawken, both of N.J.

[73] Assignee: **Hudson Surgical Design, Inc.**, Rutherford, N.J.

[21] Appl. No.: 479,363

[22] Filed: Jun. 7, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 300,379, Sep. 2, 1994, Pat. No. 5,514,139, and Ser. No. 342,143, Nov. 18, 1994, Pat. No. 5,597,379, which is a continuation-in-part of Ser. No. 300,379.

[51] Int. Cl.[6] A61B 17/56

[52] U.S. Cl. 606/80; 606/88

[58] Field of Search 606/88, 87, 86, 606/80, 82, 96

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U.S. PATENT DOCUMENTS

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Primary Examiner—Guy V. Tucker

Attorney, Agent, or Firm—Friscia & Nussbaum

[57] **ABSTRACT**

A method an apparatus for resecting a proximal tibia during a knee replacement operation is provided. The apparatus includes an ankle clamp, an alignment rod, a fixation head, cutting guide clamps having cutting guide slots therein, and a milling bit. The method includes the steps of attaching the ankle clamp about the ankle, interconnecting the distal end of the alignment rod with the ankle clamp, interconnecting the fixation head with the proximal end of the alignment rod, partially attaching the fixation head to the proximal tibia, aligning the alignment rod, completely attaching the fixation head to the proximal tibia, interconnecting the cutting guide clamps with the alignment rod, positioning the cutting guide clamps about the proximal tibia, securing the cutting guide clamps to the tibia at a proper location, removing the fixation head, placing the milling bit within the cutting guide slots, and cutting the proximal tibia with the milling bit.

19 Claims, 8 Drawing Sheets

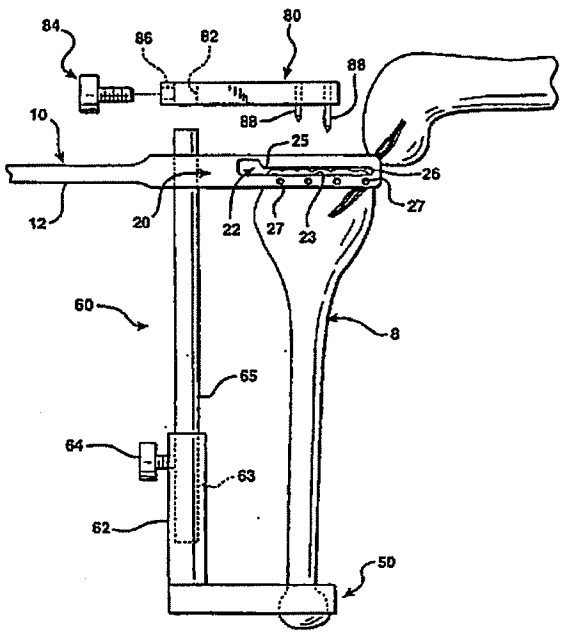
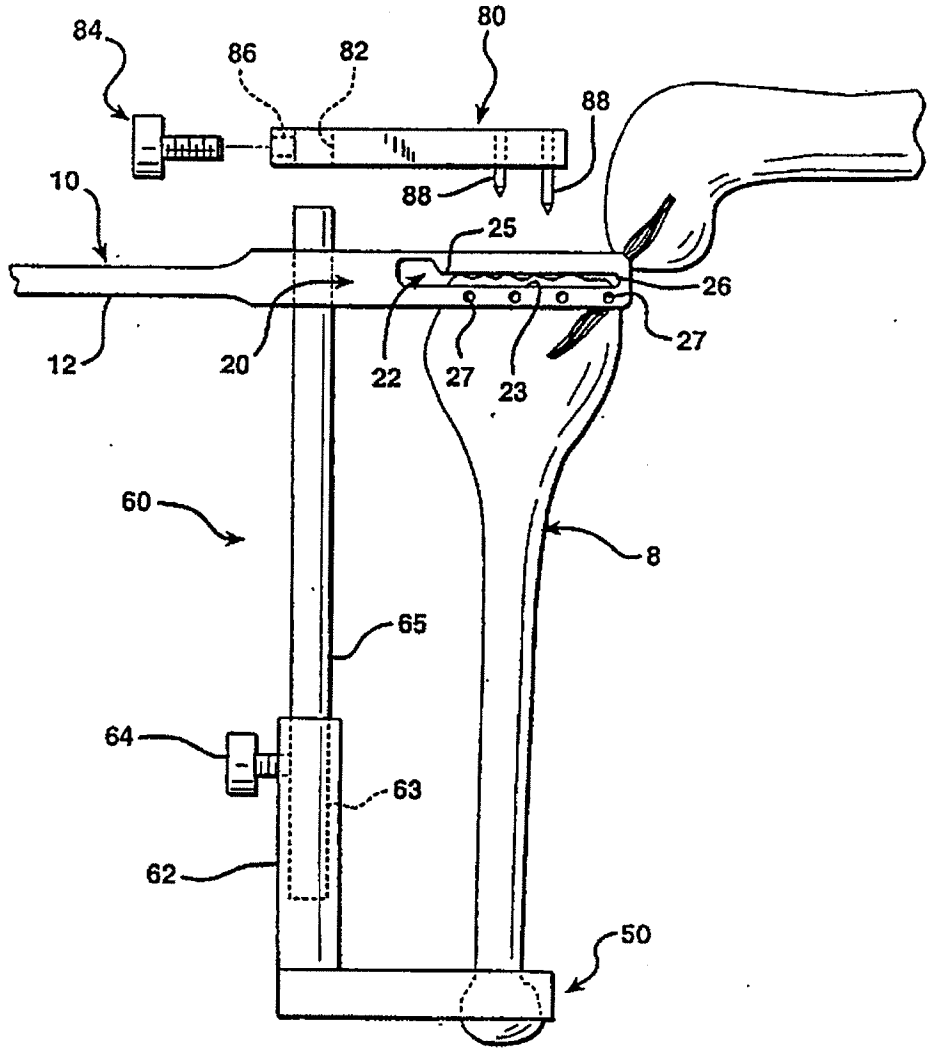


FIG. 1



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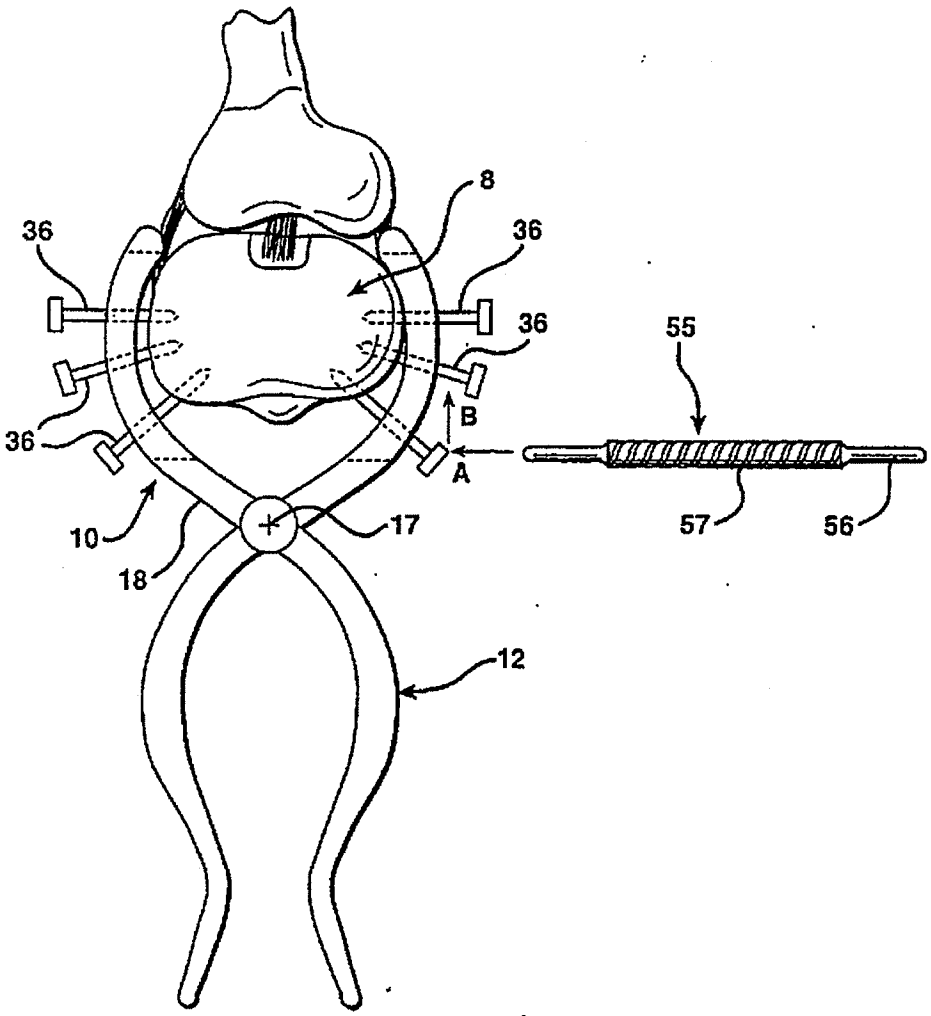

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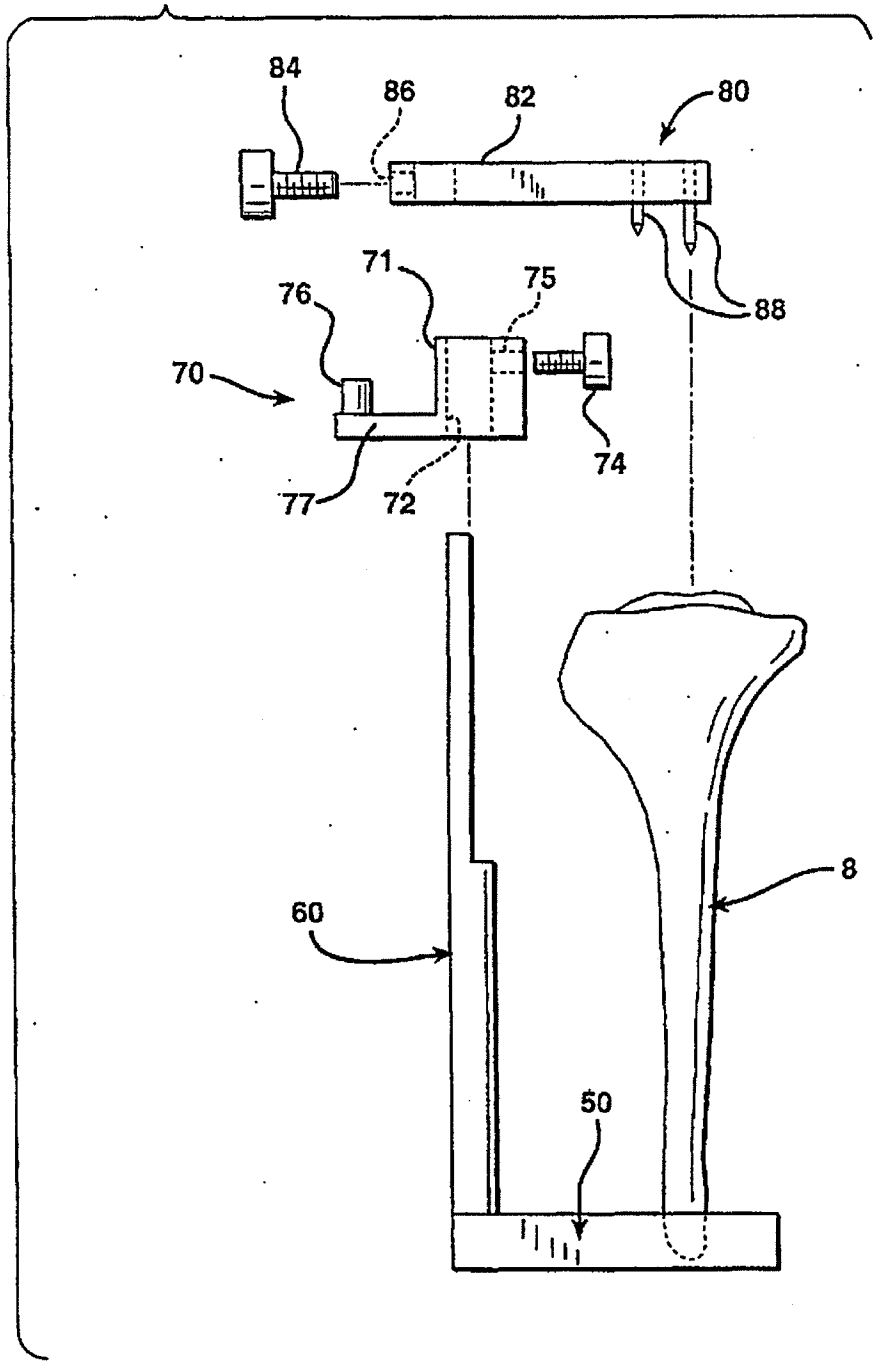

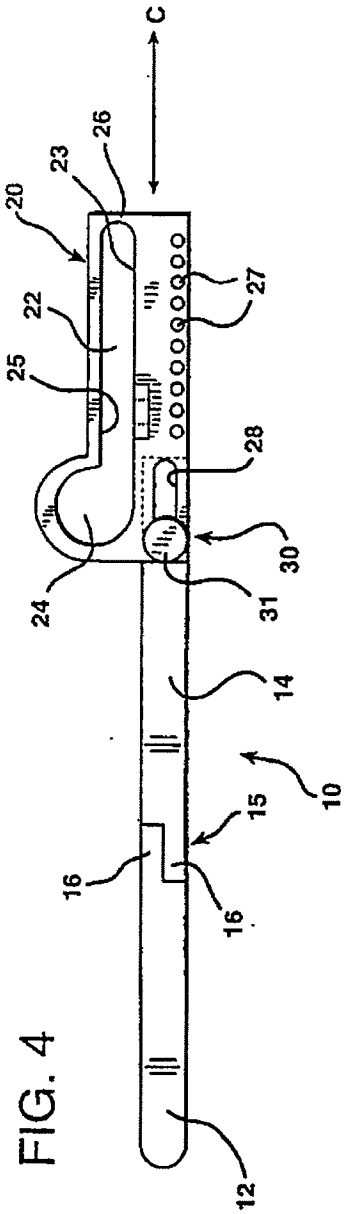
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FIG. 4

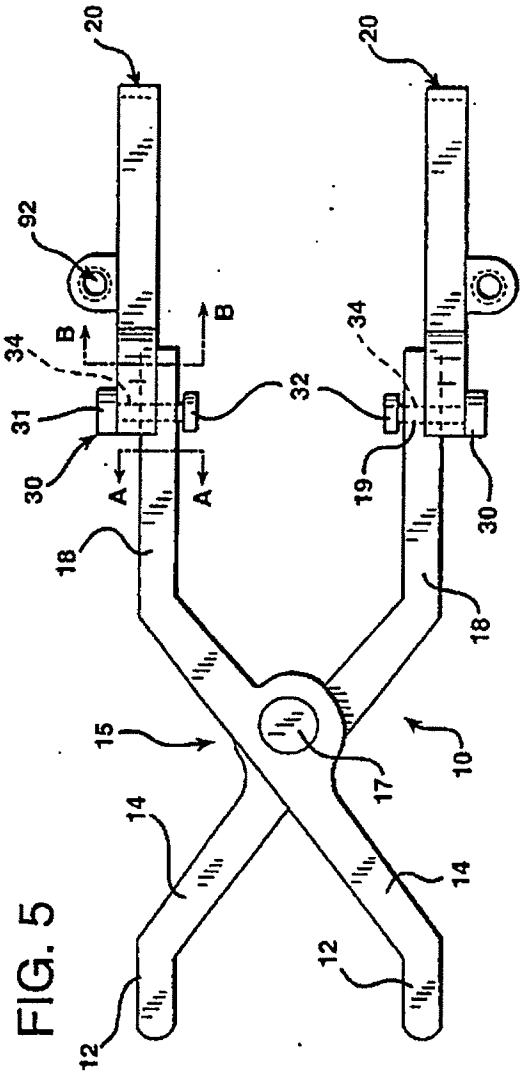
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FIG. 5

FIG. 6

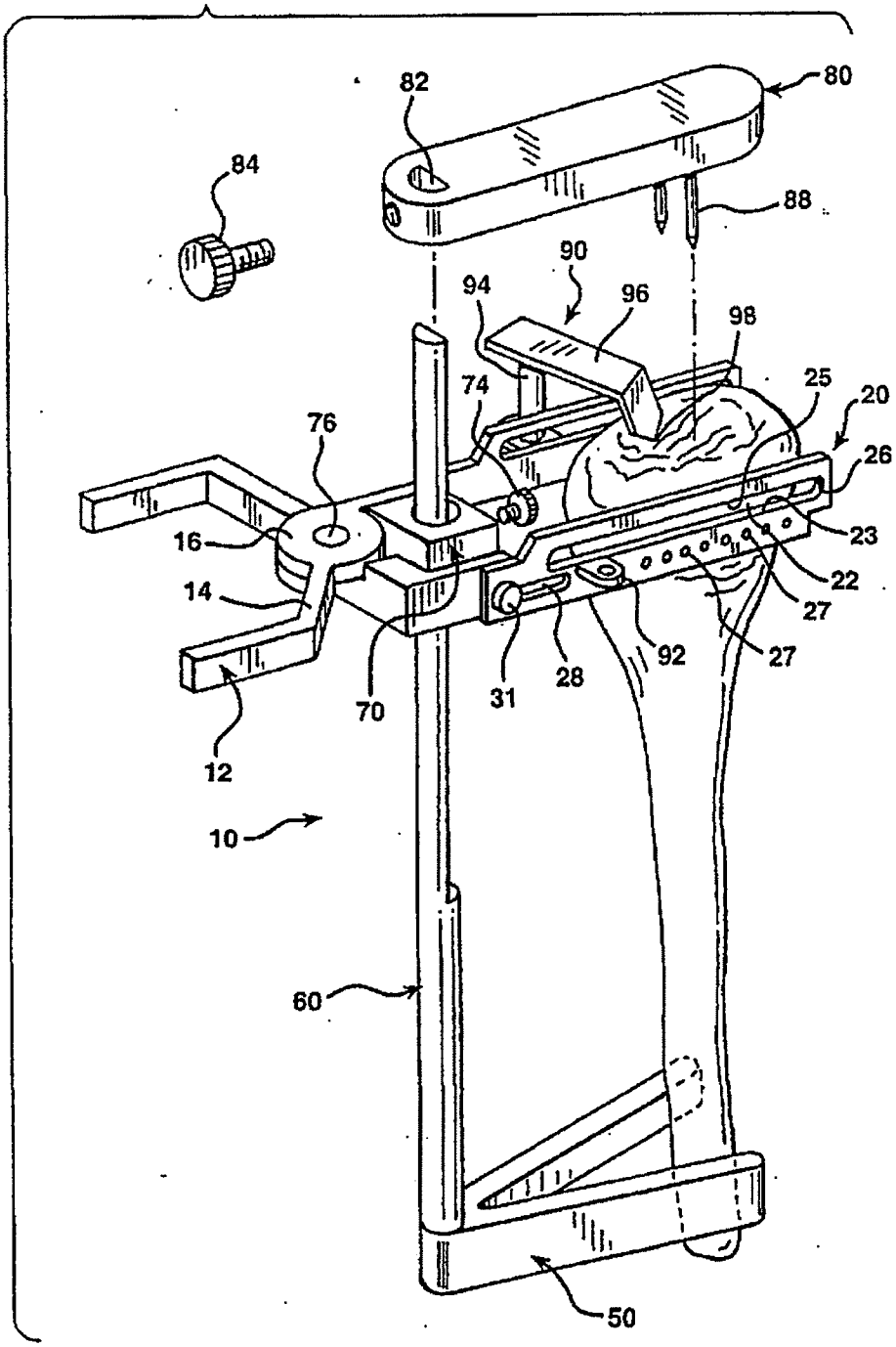
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FIG. 7

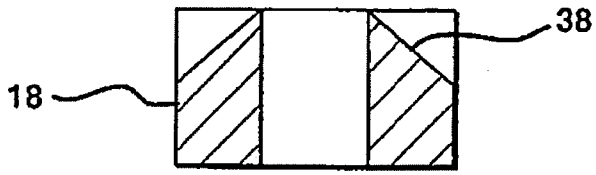


FIG. 8

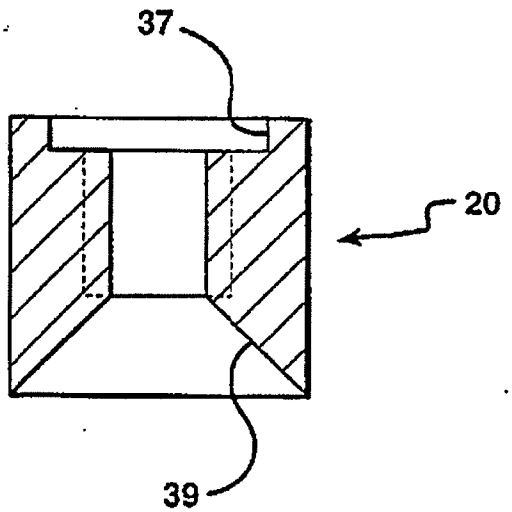


FIG. 9

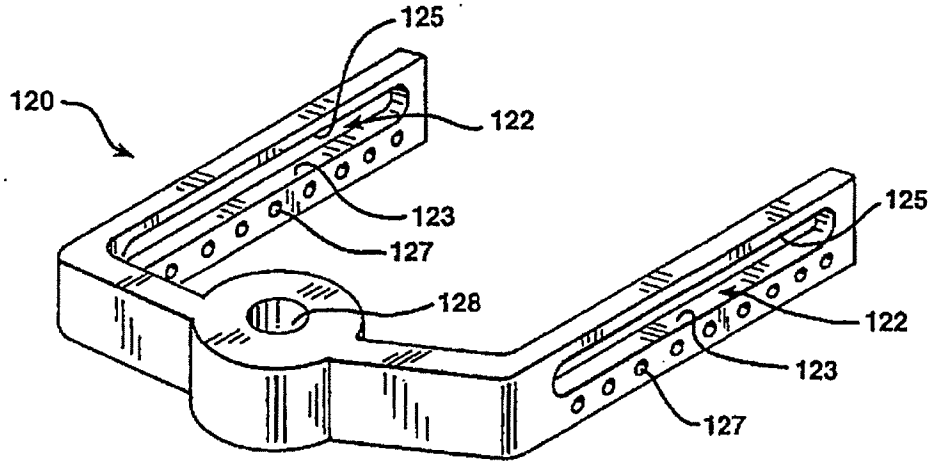
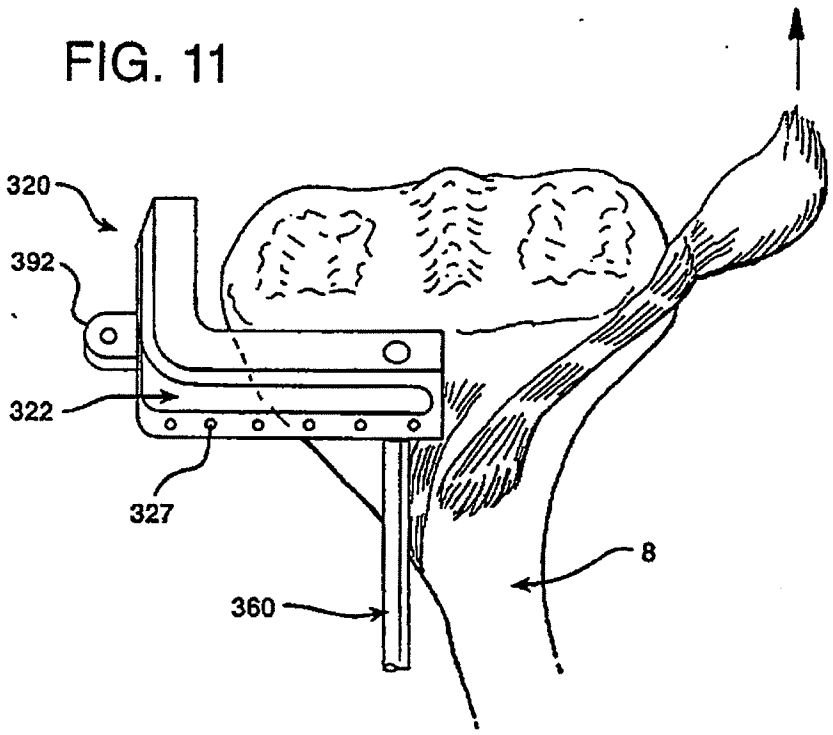


FIG. 11



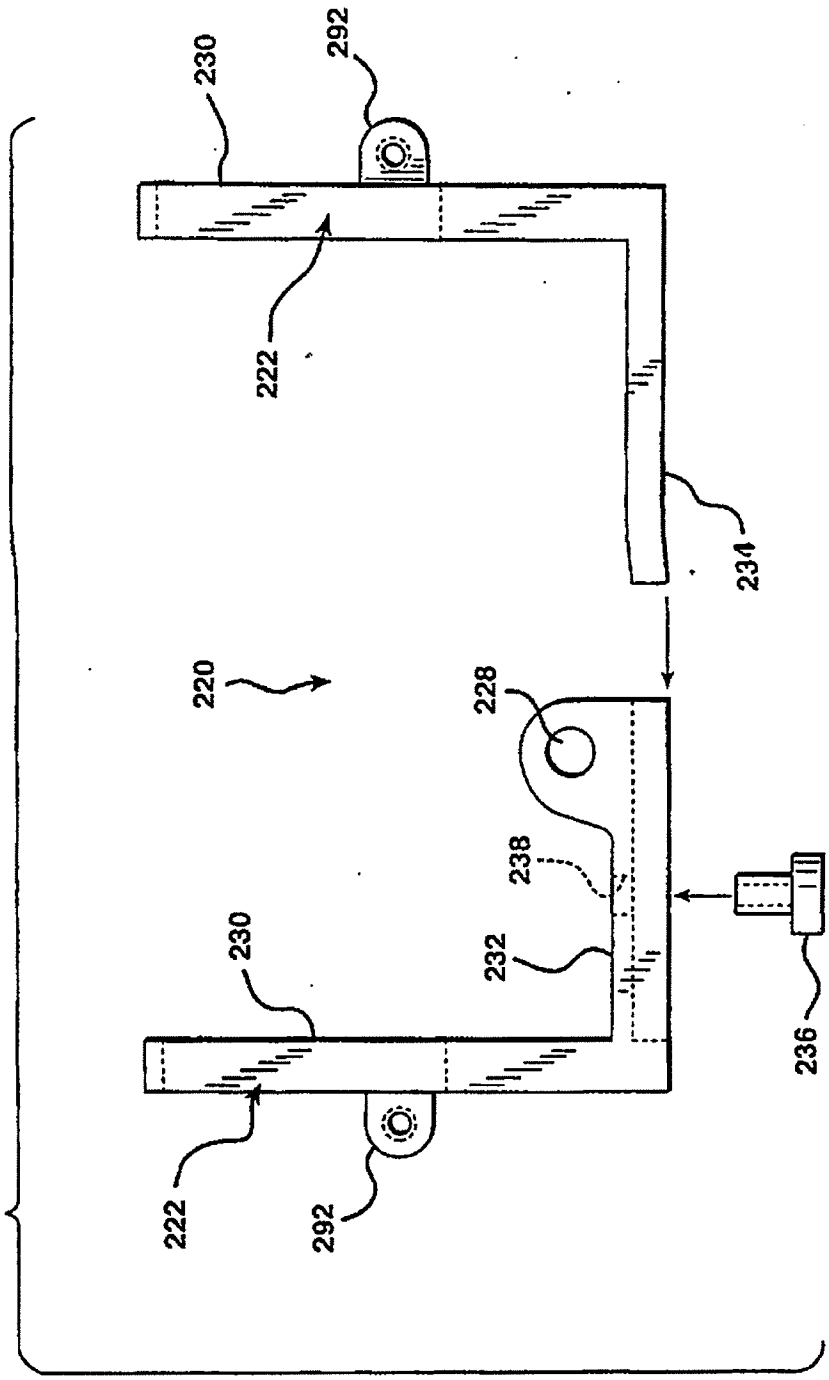


FIG. 10

METHOD AND APPARATUS FOR TIBIAL RESECTION

RELATED APPLICATIONS

This application is a continuation-in-part application of U.S. patent application Ser. No. 08/300,379, filed Sep. 2, 1994 by Goldstein, et al., now U.S. Pat. No. 5,514,139. This application is also a continuation-in-part application of U.S. patent application Ser. No. 08/342,143, filed Nov. 18, 1994, by Haines, et al., now U.S. Pat. No. 5,597,379, which is also a continuation-in-part application of U.S. patent application Ser. No. 08/300,379, filed Sep. 2, 1994, by Goldstein, et al., now U.S. Pat. No. 5,514,139. The entire disclosure of these related applications is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention generally relates to a method and apparatus for resecting a proximal human tibia to allow it to properly accept a proximal tibial prosthesis in the context of a total knee replacement operation.

2. Related Art

In the past, efforts have been made to develop methods and apparatus to resect the proximal human tibia in the context of knee replacement surgery. Many of these previous efforts, as shown in the previous relevant patents, align the tibia resection off of the intermedullary canal of the tibia, while others base alignment off of exterior alignment rods. These previous efforts also include alignment adjustment mechanisms, though these mechanisms tend to be complicated and generally inaccurate. None of the methods or apparatus that have been developed can consistently and accurately locate and properly align the tibia resection, while minimizing the cutting skill necessary to properly and safely resect the tibia, as well as smoothly cutting the tibia. Nor do any of the previous efforts disclose a simple but effective method and apparatus for efficiently resecting the proximal tibia. These past efforts include:

Stillwell, U.S. Pat. No. 4,457,307, which discloses a movable saw and saw carriage which may be mounted to the femur for resecting the femur. The saw and saw carriage are adjustable through a plurality of positions to make desired cuts in the femur. Additionally, the device may be used to cut the proximal tibia. First, the knee is extended, the collateral ligaments are tensioned and balanced, and the proximal tibia cortex is scored. Then, the knee is flexed, the saw and saw carriage readjusted, and the tibia cortex cut is completed.

Androphy, U.S. Pat. No. 4,487,203, discloses a knee resection system comprising a guide member, femur and tibia guide rods, a tibia adaptor, a tibia bar, and a femur bar. After the distal femoral condyles are resected, the guide member is attached to the tibia guide rod extending into the tibia. The tibia guide rod has a second guide at a right angle for receiving the guide member. When properly aligned, the guide member is fixed to the anterior side of the proximal tibia with pins. The tibia is then resected with an oscillating saw inserted through slots in the guide member.

Rohr, Jr., U.S. Pat. No. 4,566,488, discloses a ligament tensor device having a first member to engage the tibia and a second member to engage the intercondylar notch of the femur. This device includes means for moving the first member with respect to the second member for applying a selected tension to the ligaments of the knee joint. The device includes a tibia cutting guide which supports a tibia cutting guide head which is positioned and angled to guide the cutting of the tibial plateau. The cutting guide head includes a transverse cutting guide slot. An ankle guide bracket is attached to the lower end of the tibia cutting guide and attaches to the tibia at the ankle for supporting and aligning the tibia cutting guide structure.

Kenna, U.S. Pat. Nos. 4,653,488 and 4,787,383, disclose a tibial cutting jig for cutting a tibia after the femur has been resected. The tibia is aligned off of the resected femur through longitudinal traction and manipulation to bring the ankle under the femur to produce a tibial angle of 2.5 degrees resulting in an overall valgus alignment. The alignment is verified by sight. The knee joint is then immobilized, the transverse tibial cutting jig is pinned to the tibia, the knee is moved to flexion, and the tibia is cut by resting the saw blade on the top surface of the cutting jig.

Russell, et al., U.S. Pat. No. 4,722,330, discloses a distal femoral surface guide for mounting on an intermedullary alignment guide for use in shaping the distal femoral surface. A conventional shaping means such as an oscillating saw or hand saw is introduced into slots in the surface guide to resect the femur. The device also includes stabilizing members that extend along the sides of the femur to stabilize the device.

Fargie, et al., U.S. Pat. No. 4,736,737 discloses a tibial cutting jig having a base that interconnects with an intermedullary alignment rod installed along the axis of the tibia. The base includes outriggers carrying measurement keys for spacing the base a preselected distance above the tibia. A saw guide having slots is attached to the base and is positioned to allow for the cutting of the tibia, by means of an oscillating saw, at a selected position.

Whiteside, et al., U.S. Pat. No. 5,002,545, discloses a shaping device for shaping the tibial plateau comprising an alignment rod located anterior to the anterior cruciate ligament and along the anterior cortex of the intermedullary canal of the tibia. The shaping guide is interconnected with the rod and is adjustable with respect to the rod to control the amount of resection of the tibial plateau by raising or lowering the cutting guide surfaces. The device includes a pin which is inserted into a hole on the alignment guide for setting rotation alignment by aligning the pin with the intercondylar notch of the femur.

Poggie, et al., U.S. Pat. No. 5,250,050 discloses an apparatus for use in preparing the bone surfaces for a total knee prothesis, comprising cutting guides, templates, alignment guides, a distractor and clamping instruments. The instrument for alignment of the cutting surface for resecting the tibia includes an ankle clamp, an adjustable alignment rod, and a cutting platform. After the cutting platform is properly aligned on the tibia, it is pinned thereto and the tibia may be resected using an oscillating saw. Also disclosed is a patella resection guide comprising a scissor-type clamp having distal gripping arms, each of which define a cutting surface, and gripping teeth.

Caspari, et al., U.S. Pat. Nos. 5,263,498, 5,228,459, and 5,304,181 disclose a method and apparatus for orthoscopically preparing bone surfaces for a knee replacement. A tibial jig is attached to the tibia at just above the ankle at a lower end and to just below the tibial tubercle at an upper end. One portal is formed in the knee for insertion of an orthoscope for viewing the knee, and another portal is formed for introducing resecting instruments. A cutting platform is aligned and secured in position and a cutting module is attached. Initially, a plunge cut across the tibial eminence is produced. This procedure is repeated until the surface of the tibial plateau is covered with trails having

ridges therebetween. Thereafter, the device is passed back and forth over the tibial plateau to remove the ridges.

Morgan, U.S. Pat. No. 5,269,786, discloses a PCL oriented placement tibial guide method for guiding the tibial tunnel placement both inside and outside the knee in endoscopic ACL reconstruction.

Mikhail, U.S. Pat. No. 5,284,842, discloses a universal patellar clamp having an articular surface clamping member with a central aperture defining a centerline axis. An anterior clamping member is positioned along the centerline axis and is movable with respect to the articular clamping member to effect clamping of the patella for accepting a reamer for reaming a cavity in the patella of sufficient size to receive a patellar implant.

Johnson et al., U.S. Pat. No. 5,306,276, discloses a tibial resector guide including a tibial alignment jig having an ankle adjustment mechanism, a telescoping rod and a tibial resector guide which includes a head having a slot for receiving a bone saw. The head includes angled side walls along the slot which permit the guide to have a narrow anterior aperture, yet allow the saw blade to completely pass through the tibia.

Peterson, U.S. Pat. No. 5,342,368, discloses an intermedullary tibial resector guide which is affixed to the tibia by means of an intermedullary rod. An elongated bar extends from the intermedullary rod and carries a sleeve that supports a saw guide having a slot for receiving an oscillating saw.

Whitlock, et al., U.S. Pat. No. 5,147,365, discloses a patella osteotomy guide comprising a plier-like appliance with curved jaws for grasping a patella. A row of teeth face inwardly from the jaws and a rotating calibrated stylus measures the position of the patella with respect to an integral saw capture slot in each of the jaws. The jaws are curved with concave inner sides generally corresponding to the shape of a patella. With the guide attached to a patella, a sagittal saw can be passed through the saw capture slots to cut away a portion of the patella.

None of these previous efforts are as simple and easy to use as the present invention. Additionally, none of these previous efforts disclose all of the benefits and advantages of the present invention, nor do they teach or suggest all of the elements of the present invention.

OBJECTS AND SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide a method and apparatus for properly resecting the proximal human tibia in connection with knee replacement surgery.

It is also an object of the present invention to provide a method and apparatus for resecting the proximal human tibia which minimizes the skill necessary to complete the procedure.

It is another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which properly orients the resection of the proximal tibia.

It is even another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which is easy to use.

It is yet another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which orients the resection in accordance with what is desired in the art.

It is still yet another object of the present invention to provide a method and apparatus for resecting the proximal human tibia which minimizes the amount of bone cut.

It is a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which allows one to visually inspect the location of the cut prior to making the cut.

It is even a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which is simple in design and precise and accurate in operation.

It is yet a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which physically removes material from the proximal tibia along a surface dictated by a guide device.

It is still a further object of the present invention to provide a method and apparatus for resecting the proximal human tibia which employs a milling bit for removing material from the proximal tibia.

It is also object of the present invention to provide a method and apparatus for resecting the proximal human tibia which includes a component which is operated, and looks and functions, like pliers or clamps.

It is even another object of the present invention to provide an alternate embodiment of the method and apparatus for resecting the proximal human tibia which includes a component that resembles a U-shaped device for placing about the tibia.

It is even a further object of the present invention to provide an alternate embodiment of the method and apparatus for resecting the proximal human tibia which includes a component that resembles an adjustable, square, U-shaped device for placing about the tibia.

These objects and others are met and accomplished by the method and apparatus of the present invention for resecting the proximal tibia.

The apparatus of the present invention comprises a number of components including an ankle clamp, an alignment rod, a fixation head, cutting guide clamps having an integral attachment mechanism, and a milling bit.

The method of present invention includes the steps of attaching the ankle clamp about the ankle, interconnecting the distal end of the alignment rod with the ankle clamp, interconnecting the fixation head with the proximal end of the alignment rod, partially attaching the fixation head to the proximal tibia, aligning the alignment rod, completely attaching the fixation head to the proximal tibia, interconnecting the cutting guide clamps with the alignment rod, positioning the cutting guide clamps about the proximal tibia, securing the cutting guide clamps to the tibia at a proper location, removing the fixation head, and cutting the proximal tibia with the milling bit.

BRIEF DESCRIPTION OF THE DRAWINGS

Other important objects and features of the invention will be apparent from the following Detailed Description of the Invention taken in connection with the accompanying drawings in which:

FIG. 1 is a partially exploded side plan view of an embodiment of the tibial resection apparatus of the present invention shown attached to the tibia, wherein the cutting guide clamps are of a fixed size and directly interconnect with the alignment rod.

FIG. 2 is a top plan view of the tibial resection apparatus, shown in FIG. 1 prior to insertion of the milling bit into the apparatus.

FIG. 3 is a partially exploded side plan view of another embodiment of the tibial resection apparatus shown in FIG.

1, wherein the cutting guide clamps interconnect with the alignment rod by means of a cutting guide clamp linkage.

FIG. 4 is a side plan view of an embodiment of the cutting guide clamps shown in FIG. 1, wherein the cutting guide clamps are adjustable.

FIG. 5 is a top plan view of the cutting guide clamps shown in FIG. 4.

FIG. 6 is a perspective view of an embodiment of the tibial resection apparatus shown in FIG. 1, showing the proximal tibial referencing stylus attached to the cutting guide clamps.

FIG. 7 is a cross-sectional view of the profile of the ends of the clamp members taken along line A—A in FIG. 5.

FIG. 8 is a cross-sectional view of the profile of the ends of the cutting guides taken along line B—B in FIG. 5, the ends of the clamps mating with the ends of the cutting guides for positioning the cutting guides with respect to the clamps.

FIG. 9 is a perspective view of an alternate embodiment of a U-shaped cutting guide for use in the present invention.

FIG. 10 is a top plan view of another alternate embodiment of a square U-shaped cutting guide for use in the present invention.

FIG. 11 is a perspective view of another alternate embodiment of a partial cutting guide for use in the present invention when the patellar tendon, patella, or quad tendon interferes with placement of the cutting guide about the tibia.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIGS. 1–6, the tibial resection apparatus of the present invention includes a number of components, namely, cutting guide clamps generally indicated at 10, cutting guides generally indicated at 20, ankle clamp generally indicated at 50, alignment rod generally indicated at 60, cutting guide clamp linkage generally indicated at 70, fixation block generally indicated at 80, proximal tibial referencing stylus generally indicated at 90, and milling bit generally indicated at 55. It should be noted that the cutting guides 20 may be formed integrally with the cutting guide clamps 10 as shown in FIGS. 1 and 2, or a separate members as shown in FIGS. 4, 5 and 6. Also, the cutting guides 20 may ride the alignment 60 as shown in FIGS. 1 and 2, or they may interconnect with the alignment rod 60 by means of cutting guide clamp linkage 70 as shown in FIGS. 4, 5 and 6.

As shown in FIG. 1, the ankle clamp 50 is attached at or just above the ankle and exterior to the skin. Any conventional ankle clamp may be used to firmly engage the ankle, or to engage the tibia above the ankle, to obtain a reference point for the other components of the present invention.

The ankle clamp is interconnected with and locked into place on the alignment rod 60 in any way known in the art. Preferably, though not necessarily, the alignment rod 60 is vertically adjustable with respect to the ankle clamp 50. This vertical adjustment can be achieved at the ankle clamp 50, at the interconnection of the ankle clamp 50 and the alignment rod 60, or within the alignment rod 60 itself. As shown in FIG. 1, the alignment rod includes a first lower end 62 having an aperture 63 extending vertically therein for telescopically receiving a second upper end 65 of the alignment rod 60. A set screw 64 is provided for fixing the upper end 65 with respect to the lower end 62.

The fixation block 80 is interconnected with an upper end of the alignment rod 60 by means of an aperture 82 in the fixation block 80 sized to receive the alignment rod 60 therethrough, or in any other manner known in the art. A set screw 84 may be provided to extend into the fixation block 80, through set screw aperture 86 in fixation block 80, to contact the alignment rod 60, to lock the fixation block 80 onto the alignment rod 60. The fixation block 80 additionally includes apertures extending vertically therethrough for receiving fixation pins 88 for affixing the fixation block 80 to the proximal tibia 8.

In operation, the ankle clamp 50 is attached about the ankle, or about the tibia just above the ankle, on the exterior of the skin. The fixation block 80 is already interconnected with the alignment rod 60. It is preliminarily positioned over the proximal tibia 8, and one of the fixation pins 88 is driven into the proximal tibia 8. Thereafter, the alignment rod 60 is adjusted to establish proper varus/valgus alignment and flexion/extension angulation as is conventionally known. Upon proper alignment of the alignment rod 60, the other fixation pin 88 is driven into the proximal tibia 8 to completely fix the fixation block 80 to the proximal tibia 8 to lock in the proper alignment of the alignment rod 60. Then, the fixation block 80 may be locked into position on the alignment rod 60.

After properly aligning and locking in the alignment of the alignment rod 60, the cutting guide clamps 10 and the cutting guides 20 may be employed. The cutting guide clamps 10 are interconnected with the alignment rod 60 by means of cutting guide linkage 70. Alternatively, the cutting guide clamps 10 could directly interconnect with the alignment rod 60 through apertures in the cutting guide clamps 10 as shown in FIGS. 1 and 2. As shown in FIG. 3, the cutting guide clamp linkage 70 comprises a body 71 having an alignment rod aperture 72 for receiving and riding the alignment rod 60 and a pivot locking set screw 74 which extends into the cutting guide clamp linkage 70 through set screw aperture 75 for contacting the alignment rod 60 and locking the cutting guide clamp linkage 70 with respect to the alignment rod 60. It should be pointed out that it may be desirable for the alignment rod 60 to have a flattened surface extending longitudinally along the alignment rod 60 for coacting with set screw 74 for maintaining proper alignment between the cutting guide clamp linkage 70 and the alignment rod 60.

The cutting guide clamp linkage 70 also includes a pivot shaft 76 rigidly interconnected with the body 71 of the cutting guide clamp linkage 70 by member 77 to position the pivot shaft 76 a distance away from the body 71 such that the cutting guide clamps 10 can be interconnected with the pivot shaft 76 and can be properly utilized without interfering with the body 71 of the cutting guide clamp linkage 70.

After the alignment rod 60 is properly aligned and locked into position, the cutting guide clamp linkage 70 is moved into its approximate desired position at the proximal tibia 8. It should be noted that the cutting guide clamp linkage 70 of present invention is positioned on the alignment rod 60 at the beginning of the procedure, prior to aligning the alignment rod 60, and prior to interconnecting the fixation block 80 with the alignment rod 60. However, it is within the scope of the present invention to provide a cutting guide clamp linkage 70 which is attachable to the alignment rod 60 after the alignment rod 60 has been aligned and locked into position.

After the cutting guide clamp linkage 70 is preliminarily approximately located, it is locked into place on the alignment rod 60. Thereafter, the cutting guide clamps 10 may be interconnected with the pivot shaft 76 by means of corresponding pivot apertures 17 in the cutting guide clamps 10.

As shown in FIGS. 4 and 5, the cutting guide clamps 10 include opposing hand grips 12 for grasping and manipulating the cutting guide clamps 10. Cross bar members 14 extend from the hand grips 12 to clamp members 18. The cross bar members 14 cross over each other at cross over point 15 whereat the cross bar members 14 have mating recessed portions 16 which function to maintain the hand grips 12 in the same plane as the clamp members 18. At the cross over point 15, the cross bar members 14 can pivot with respect to each other such that movement of the hand grips 12 towards each other moves the clamp members 18 together, and likewise, movement of the hand grip members 12 away from each other serves to move the clamp members 18 apart in the same manner as scissors or pliers. At the cross over point 15, the cross bar members 14 have corresponding pivot apertures 17 for receiving the pivot shaft 76 of the cutting guide clamp linkage 70. Thus, the cutting guide clamps 10 pivot about the pivot shaft 76 of the cutting guide clamp linkage 70. It should be noted that the cross bar members 14 could be interconnected with each other by a rivet or other means known in the art, or could be entirely independent pieces which coact as set forth above only upon being seated on pivot shaft 76.

The clamp members 18 of the cutting guide clamps 10 include cutting guide adjustment screw apertures 19 at the far ends thereof for receiving A-P adjustment screws 30 for adjustably interconnecting the cutting guides 20 with the clamp members 18, for adjustable movement in the direction shown by arrow C in FIG. 4. The clamp members 18 may be adjustably interconnected with the cutting guides 20 in any way known in the art. In one embodiment, the cutting guide adjustment screw apertures 18 are threaded and the cutting guides 20 have corresponding elongated apertures 28 extending over a portion of the length thereof for receiving the A-P adjustment screws at a desired location therealong. The A-P adjustment screws include a head 31, a retaining head 32, and a threaded shaft 34. When the cutting guides 20 are positioned correctly with respect to the clamp members 18, the A-P adjustment screws 30 are tightened down to lock the cutting guides 20 onto the clamp members 18 by actuating the head 31 to turn down the threaded shaft 34 with respect to the clamp member 18. Note the retaining head 32 of the A-P adjustment screws prevent the shaft 34 from being backed off out of engagement with the clamp member 18.

As shown in FIGS. 7 and 8, respectively, the clamp members 18 are shaped with opposing interior edges having chamfers 38 and the opposite exterior edges of the cutting guides 20 have mating recesses 39, both of said profiles extending along the contacting surfaces of the clamp members 18, as seen along line A—A in FIG. 5, and the cutting guides 20, as seen along line B—B in FIG. 5, to maintain a proper planar alignment therebetween. It should of course be noted that any other method known in the art may be employed to maintain the clamp members 18 and the cutting guides 20 in alignment. Additionally, the cutting guides 20 may include A-P adjustment screw recesses 37 for receiving the head 31 of the A-P adjustment screw 30.

The cutting guides 20 further include tibia attachment means for attaching the cutting guides 20 to the tibia 8. Any known attachment means may be employed to attach the cutting guides 20 to the tibia 8. As shown in FIGS. 2 and 4, a preferred attachment means for attaching the cutting guides 20 to the tibia 8 are pins 36 extending through pin apertures 27 in the cutting guides 20. The pins 36 may be captured in the pin apertures 27, or they may be entirely separate. Preferably, means exist on the cutting guides 20 for preliminarily attaching the cutting guides 20 to the tibia 8 prior to pinning the cutting guides 20 thereto, so that after proper positioning of the cutting guides 20, the hand grips 12 can be actuated by squeezing the hand grips 12 together to contact the cutting guides 20 against the tibia 8 so that the cutting guides 20 are preliminarily attached to the tibia 8. Such means may include a plurality of small pins captured by the cutting guide 20, or any other suitable means. After the preliminary attachment of the cutting guides 20 to the tibia 8, final attachment may be made by attachment pins 36 or by any other means known in the art.

The cutting guides 20, importantly, include cutting slots 22 which each comprise lower cutting slot guide surface 23 and upper cutting slot retaining surface 25, as well as cutting slot entrance and exit 24 at one end thereof and cutting slot end wall 26 at the other end thereof. The cutting slot 22 is of a length sufficient to extend across the proximal tibia 8, at a desired angle to the intermedullary canal, at the widest point of the proximal tibia 8, to allow the entire upper surface of the proximal tibia 8 to be cut. The cutting slot 22 is of a size sufficient to receive a cylindrical milling bit 55 such as that shown in FIG. 2 and described in co-pending patent application No. 08/300,379, filed Sep. 2, 1994 by Goldstein, et al. The milling bit 55 comprises central cutting portion 57 having helical cutting teeth along its length for cutting bone. The milling bit 55 further comprises spindles 56 extending from the central cutting portion 57 for supporting the central cutting portion 57.

The milling bit 55 is inserted into and received in the cutting slot 22 through cutting slot entrance 24, along the direction shown by arrow A in FIG. 2. Note that the cutting slot entrance 24 may by of a wider slot area or an upturned portion of the slot 22 or the milling bit 55 may merely be inserted and removed from the slot 22 at an end thereof. The spindles 56 extend through and coact with the lower cutting guide surface 23 and the upper retaining surface 25 of the cutting slot 22 to guide the milling bit 55 along the cutting slot 22 to resect the proximal tibia 8, along the direction shown by arrow B in FIG. 2. At an end of one or both of the spindles 56 is a means for engaging the milling bit 55 with a drive means such as an electric drill, or other drive means. This engagement means may include a hexagonal head on one of the spindles, or any other suitable method of engagement known in the art. Additionally, bushings may be employed, either on the milling bit 55 or captured by the cutting slot 22, to provide a non-metallic bearing between the spindles 56 of the milling bit 55 and the cutting slot 22 to avoid galling and to insure smooth articulation of the milling bit 55 along the cutting slots 22. Importantly, the configuration of the milling bit 55 may be varied in accordance with what is known in the art, as long as the cutting device can follow the cutting path of the cutting slot to resect the proximal tibia. Additionally, it should also be pointed out that other cutting tools may be used in accordance with present invention, including an oscillating or reciprocating saw or other means for resecting the tibia by following the cutting slots on the cutting guides.

After the cutting guide clamps 10 are preliminarily located along the alignment rod 60, the cutting guides 20 are adjusted with respect to the clamp members 18 for proper anterior-posterior positioning to extend along the proximal tibia 8 for guiding the milling bit 55. Importantly, the cutting slots 22 should extend beyond the edges of the proximal tibia 8. Once proper anterior-posterior alignment is obtained, the cutting guides 20 may be locked into place on the clamp members 18.

Thereafter, a proximal tibial referencing stylus 90 may be attached to a referencing bracket 92 on the cutting guides 20.

The referencing bracket 92 may be positioned in any location on the cutting guides 20, or on any other convenient component of the tibia resection system of the present invention. Alternatively, the referencing stylus 90 may be formed as part of a component of the present invention, or as a separate component which could function merely by contacting the cutting guides 20 of the present invention of any other component thereof. The referencing stylus 90 shown in FIG. 6 includes stylus body 94 which may be interconnected with the referencing bracket 92 in any manner known in the art, preferably by a quick release and connect mechanism or a threaded connection. The stylus body 94 supports a stylus arm 96, which is rotatable with respect to the stylus body 94 and configured to extend out and down from the stylus body 94 to contact the proximal tibia 8 at a tip 98 of the stylus arm 96. The stylus body 94, arm 96 and tip 98 are sized to contact the proximal tibia 8 to reference the positioning of the cutting guides 20 to cut the proximal tibia at a proper distance below the proximal tibia 8 as is known in the art. The stylus arm 96 may include more than one tip 98, such other tips extending down from the stylus body 94 in varying distances.

In operation, one determines the desired location of the stylus tip 98, unlocks the cutting guide clamp linkage 70 to permit the linkage 70 to move up and down the alignment rod 60, and places the tip 98 on the lowest point of the proximal tibia 8 to reference the position of the of the cutting guides with respect to the proximal tibia 8 and with respect to the alignment rod 60. Thereafter, the cutting guide clamp linkage 70 is locked to the alignment rod 60 to lock the cutting guides 20 into the proper position on the alignment rod 60, and accordingly, into proper position with respect to the proximal tibia 8. Thereafter, the hand grips 12 are actuated to press the cutting guides 20 against the proximal tibia 8 to preliminarily lock them into position on the proximal tibia 8. Next, the cutting guides 20 are fixed to the proximal tibia 8 by pins 36 or any other desired fixation means. The fixation block 80 can then be removed from the proximal tibia 8, and the proximal tibia 8 may be resected.

The cutting operation is similar to the cutting operation set forth in co-pending patent application No. 08/300,379, filed Sep. 2, 1994 by Goldstein, et al. Essentially, the cutting operation comprises inserting the milling bit 55 into the cutting guide slots 22 through the slot entrance/exit 24 to position the central cutting portion 57 between the cutting guides 20, the spindles 56 extending through the cutting guide slots 22. After the milling bit 55 is positioned, the drive means may be interconnected therewith, actuated, and the milling bit 55 moved along the cutting slots 22 to resect the proximal tibia 8.

It should be noted that a handle may be provided for attachment to the spindle which is not driven so that such spindle may be guided evenly through the cutting slots 22 to facilitate the cutting procedure. Alternatively, a handle can be provided which interconnects with both spindles to further facilitate control of the milling bit 55 during the cutting procedure. Additionally, the bushings that fit over the spindles 56 of milling bit 55 and ride in the cutting slots 22 may be captured in the ends of the handle and the milling bit received therethrough.

Additionally, it should be pointed out that it is within the scope of the present invention to modify the cutting slots 22 such that the upper retaining surface is eliminated, and the milling bit 55 merely follows the lower cutting guide surface 23. With the cylindrical milling bit 55 herein described, this is especially viable as the milling bit 55 tends to pull down into the bone as it is cutting, thereby primarily utilizing the lower cutting guide surface 23 of the cutting guide 20.

As shown in FIGS. 9-11, various other embodiments of the cutting guides are considered within the scope of the present invention. The cutting guide 120 shown in FIG. 9 is of a generally U-shaped configuration, having cutting guide slots 122, lower cutting guide surface 123, upper retaining surface 125, pin apertures 127 and alignment rod aperture 128. This cutting guide 120 is used in the same manner as the cutting guides hereinbefore described, the differences being that the cutting guide 120 interconnects directly with the alignment rod and that various size cutting guides must be provided to accommodate various sized tibias.

Likewise, the cutting guide 220 shown in FIG. 10 operates in the same manner as the cutting guide devices hereinbefore described, but it does not include cutting guide clamps. The cutting guide 220 includes cutting slots 222, and it interconnects directly with alignment rod by means of aperture 228. The distance between facing members 230 can be adjusted by moving base members 232 and 234 with respect to each other to size the cutting guide 220 for the tibia to be cut. Upon proper sizing, the base members 232 and 234 may be locked with respect to each other by set screw 236 or any other means known in the art.

FIG. 11 shows an embodiment of the cutting guide for use when the patellar tendon, the patella, or the quad tendon interferes with the placement of the other cutting guides of the present invention. As shown in FIG. 11, the cutting guide 320 may be directly interconnected with the alignment rod, and positioned on the tibia as hereinbefore set forth. Basically, this embodiment of the invention includes only one cutting guide. The cutting guide 320 and the cutting guide slot 322 may be wider than in the previous embodiments to help stabilize the milling bit in operation. In this embodiment, the milling bit may be first plunged across the tibia, and then moved therealong. The milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to the tissue about the tibia. Additionally, a support member, not shown, could be provided to extend from the cutting guide 320, over and across the tibia to the other side thereof where it could have a slot to capture the milling bit and provide additional support thereto.

Having thus described the invention in detail, it is to be understood that the foregoing description is not intended to limit the spirit and scope thereof. What is desired to be protected by Letters Patent is set forth in the appended claims.

What is claimed is:

1. A method for resecting a proximal tibia comprising the steps of:

attaching an ankle clamp about an ankle;

interconnecting an alignment rod at a distal end thereof with the ankle clamp;

interconnecting a fixation head with a proximal end of the alignment rod;

partially attaching the fixation head to the proximal tibia;

aligning the alignment rod;

completely attaching the fixation head to the proximal tibia;

interconnecting cutting guide clamps with the alignment rod;

positioning the cutting guide clamps about the proximal tibia;

securing the cutting guide clamps to the tibia at a proper location;

removing the fixation head from the tibia; and

cutting the proximal tibia with a milling bit.

2. The method of claim 1 wherein the step of interconnecting the cutting guide clamps with the alignment rod further includes the steps of:

positioning a cutting guide linkage along the alignment rod; and

interconnecting the cutting guide clamps with the cutting guide linkage by means of locating pivot apertures in the cutting guide clamps onto a pivot shaft formed on the cutting guide linkage.

3. The method of claim 2 wherein the step of positioning the cutting guide clamps about the proximal tibia comprises manipulating hand grips interconnected with the cutting guide clamps to move the cutting guide clamps against the proximal tibia.

4. The method of claim 3 wherein the step of positioning the cutting guide clamps about the proximal tibia further includes the step of adjusting the cutting guide clamps with respect to cutting guide members extending from the hand grips.

5. The method of claim 4 wherein the step of cutting the proximal tibia with a milling bit comprises the steps of:

inserting the milling bit into guide slots formed in the cutting guide clamps;

engaging the milling bit with drive means;

capturing ends of the milling bit with handle means; and

guiding the milling bit through the guide slots in the cutting guide clamps to resect the proximal tibia.

6. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to a tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means, the cutting guide means comprising two members in opposing relationship including:

guide surfaces defining linear paths located within cutting guide slots formed in the cutting guide means;

entrance areas comprising upturned slot areas communicating with the cutting guide slots for receiving a milling bit;

the cutting guide means including hand grips, mating cross bars having pivot apertures and clamp members, the cutting guide means adjustably interconnected with the clamp members;

fixation means for affixing the cutting guide means to a tibia; and

milling means for cutting a tibia, the milling means received and guided by the cutting guide slot of the cutting guide means for resecting a tibia.

7. The apparatus of claim 6 further including cutting guide linkage means for interconnecting the cutting guide means with the alignment means, the cutting guide linkage means comprising an aperture for receiving the alignment rod and a post for inserting through the pivot apertures of the mating cross bars of the cutting guide means.

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means, the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia, the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

milling means for cutting the tibia, the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

9. The apparatus of claim 8 wherein the guide surfaces of the cutting guides are located within cutting guide slots formed in the cutting guides, the cutting guide slots receiving and guiding the milling means for resecting the tibia.

10. The apparatus of claim 9 wherein the guide surfaces of the cutting guide slots define a linear cutting path.

11. The apparatus of claim 8 wherein cutting guides have corresponding cutting guide slots therein for receiving and guiding the milling means for resecting the tibia.

12. The apparatus of claim 11 wherein the cutting guide slots further include an entrance area for receiving the milling means comprising an enlarged slot area at an end of the guide slots.

13. The apparatus of claim 11 wherein the cutting guide slots further include an entrance area for receiving the milling means comprising an upturned slot area at an end of the guide slots.

14. The apparatus of claim 11 wherein the cutting guide means further comprise hand grips, mating cross bars having pivot apertures and clamp members, the cutting guide means adjustably interconnected with the clamp members.

15. The apparatus of claim 14 further including cutting guide linkage means for interconnecting the cutting guide means with the alignment means, the cutting guide linkage means comprising an aperture for receiving the alignment rod and a post for inserting through the pivot apertures of the mating cross bars of the cutting guide means.

16. A method for resecting a proximal tibia comprising the steps of:

interconnecting an alignment rod with the tibia at proximal and distal ends of the tibia;

interconnecting cutting guide means with the alignment rod;

positioning the cutting guide means in opposing relation along sides of the proximal tibia;

securing the cutting guide means to opposing sides of the tibia;

cutting the proximal tibia with a milling bit by moving the milling bit along cutting guide surfaces on the cutting guide means.

17. The method of claim 16 wherein the step of positioning the cutting guide means in opposing relation across the proximal tibia comprises manipulating hand grips interconnected with the cutting guide means to move the cutting guide means against the proximal tibia.

18. The method of claim 17 wherein the step of positioning the cutting guide means in opposing relation across the proximal tibia further includes the step of adjusting the cutting guide means with respect to the hand grips.

19. The method of claim 18 wherein the step of cutting the proximal tibia with a milling bit comprises the steps of:

inserting the milling bit into guide slots formed in the cutting guide means;

engaging the milling bit with drive means;

capturing ends of the milling bit with handle means; and

guiding the milling bit through the guide slots in the cutting guide means to resect the proximal tibia.

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EXHIBIT B

REDACTED CONFIDENTIAL DOCUMENT

EXHIBIT C

REDACTED CONFIDENTIAL DOCUMENT

EXHIBIT D

REDACTED CONFIDENTIAL DOCUMENT

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

HUDSON SURGICAL DESIGN, INC. Plaintiff, v. ZIMMER HOLDINGS, INC.; ZIMMER, INC.; RUSH SYSTEM FOR HEALTH; AND RUSH UNIVERSITY MEDICAL CENTER, Defendants.	Civ. No. 08-CV-1566 Judge Virginia M. Kendall Magistrate Judge Nan R. Nolan

HUDSON SURGICAL DESIGN, INC.'S RESPONSES TO DEFENDANT RUSH UNIVERSITY MEDICAL CENTER'S FIRST SET OF INTERROGATORIES (NOS. 1 – 15)

Hudson Surgical Design, Inc. ("Hudson") hereby objects to Rush University Medical Center's ("RUMC") First Set of Interrogatories to Plaintiff.

GENERAL OBJECTIONS

1. Hudson objects to any of RUMC's interrogatories that call for documents or information subject to the attorney client privilege and/or the doctrine of work product immunity, or any other privilege. Any documents or information withheld from production on the basis of privilege will be identified in a withheld document list that will be exchanged with RUMC in accordance with the Court's scheduling order.

2. Hudson objects to RUMC's interrogatories to the extent they are premature and/or not sufficiently limited or reasonably calculated to lead to discovery of admissible evidence and are, therefore, overly broad and unduly burdensome. Hudson is willing, however, to confer with RUMC in an effort to resolve any disagreements between the parties relating to the timing, scope, breadth and relevancy of RUMC's interrogatories.

responsive documents exist and are in the possession, custody or control of Hudson, they will be produced.

8. Provide a full description of any notice that You provided to RUMC or RSH relating to the patents-in-suit or any other information supporting Your contention that either RUMC or RSH was aware of the patents-in-suit before the initiation of this lawsuit. Your response should identify all documents supporting your contention and Identify all persons with knowledge of your contention.

RESPONSE:

See General Objections Nos. 1, 4, 5, 6, 7, 8, 9 and 11. Hudson objects to this interrogatory to the extent it seeks information that is subject to the attorney-client privilege and/or the attorney work product immunity. Furthermore, Hudson objects to the phrase "any notice...provided to RUMC or RSH relating to the patents-in-suit" as vague and ambiguous. To the extent this phrase can be understood, Hudson objects to it as requiring a legal conclusion. Hudson also objects to this interrogatory as premature. Hudson's investigation into the subject matter of this interrogatory is ongoing. Hudson has served written discovery requests seeking information on RUMC's and RSH's awareness of the patents-in-suit, but has not received adequate responses to these requests. Hudson reserves the right to supplement and/or to amend its answer to this interrogatory based on information obtained in discovery.

Subject to and limited by these objections, Hudson answers this interrogatory as follows: Hudson did not provide RUMC or RSH with written notice of infringement of the patents-in-suit prior to March 18, 2008. As presently advised, Hudson believes that RUMC was aware of the patents-in-suit prior to March 18, 2008. Hudson believes that Dr. Richard A. Berger and/or Dr. Aaron Rosenberg may have knowledge pertaining to the subject matter of this interrogatory.

9. Provide a full description of any sale or license of any minimally invasive quadriceps-sparing surgical techniques for total knee replacement or devices used in such a knee replacement by You. Your response should state the first such sale or license, the amount of proceeds stemming from any such sale or license on a per/month basis from the first sale until

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

HUDSON SURGICAL DESIGN, INC., Plaintiff, v. ZIMMER HOLDINGS, INC., ZIMMER, INC., RUSH SYSTEM FOR HEALTH and RUSH UNIVERSITY MEDICAL CENTER, Defendants.	)	Civil Action No. 08 C 1566 Judge Virginia M. Kendall Magistrate Judge Nan R. Nolan

Rush University Medical Center's
First Supplemental Response to Hudson's First Set of Interrogatories

OBJECTIONS

1. Rush University Medical Center ("RUMC") objects to the definition of "Rush Medical" as provided, and does not respond to any of the interrogatories pursuant to that definition. In its responses, any reference to Rush Medical or RUMC means Rush University Medical Center and only Rush University Medical Center.

2. RUMC objects to the definition of "Rush Health" as provided, and does not respond to any of the interrogatories pursuant to that definition. In its responses, any reference to Rush Health or RSH means Rush System for Health and only Rush System for Health.

3. RUMC objects to the definition of the term "Accused Instruments" as being vague, ambiguous, and potentially requiring legal conclusions to be determined, especially as that

definition, as stated in the interrogatories, is "not limited to" anything. In responding to these interrogatories, RUMC reads "Accused Instruments" as "NexGen Complete Knee Solution Quad-Sparing Instrumentation."

4. RUMC objects to the definition of the term "Accused Techniques" at least on the same bases as it objects to the term "Accused Instruments" as the former definition incorporates the latter. RUMC further objects that the phraseology "minimally invasive quadriceps-sparing surgical techniques for total knee replacement" is vague and overbroad.

5. RUMC objects to the definition of the term "Accused Implants" at least on the same bases as it objects to the terms "Accused Instruments" and "Accused Techniques" as the first definition incorporates the latter two.

6. RUMC objects to the definitions of the terms "persons" and "acts of a person" and does not respond pursuant to those definitions but rather pursuant to normal usage.

7. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent they seek information protected from discovery by the attorney-client privilege, work product immunity, and/or any other applicable privilege or immunity. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any such applicable privilege or immunity.

8. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent that they seek to impose any obligation on RUMC in addition to or different from those imposed by the Federal Rules of Civil Procedure, the Local Civil Rules for the Northern District of Illinois and/or any Order of the Court or agreement between the parties, and limits its responses to that required.

9. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent that they seek to impose any obligation on RUMC to disclose information not in its possession, custody or control.

10. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent they are overly broad, unduly burdensome, not relevant to any claims or defenses in this action, not reasonably calculated to lead to the discovery of admissible information, and seek material not within the permissible scope of discovery.

11. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent they prematurely seek information and contentions prior to the completion of the discovery necessary for RUMC to fully respond.

12. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds and to the extent they consist of multiple discrete parts, which should be counted as separate interrogatories pursuant to Fed. R. Civ. P. 33. RUMC reserves the right to object to further interrogatories from Plaintiff as in excess of the number allowed.

13. To the extent not specifically objected to above, RUMC objects to Plaintiff's definitions on the grounds and to the extent they purport to alter the plain meaning or scope of any interrogatory, on the grounds that such alteration renders the interrogatory vague, ambiguous, unduly broad and uncertain.

14. RUMC does not concede the relevance or materiality of the subject matter of any of these interrogatories or RUMC's Responses thereto. Further, RUMC does not concede the relevancy, materiality or admissibility of any particular document identified in response to any of Plaintiff's interrogatories. RUMC reserves the right to object to any further discovery or to the

admissibility of any matter or document at trial.

15. RUMC objects to interrogatories as vague, overbroad, and unduly burdensome to the extent that their temporal scope is not limited to after the filing of this action because Hudson has not established that it states a claim for patent infringement and/or damages for any time before the filing of this action, and therefore RUMC limits, where applicable, its response to information after the filing of this action.

16. RUMC objects to Plaintiff's First Set of Interrogatories on the grounds that they are not signed, as required by the Federal Rules of Civil Procedure. As such, RUMC has no obligation to respond to Plaintiff's First Set of Interrogatories.

17. The discovery period established by the Court is still ongoing. RUMC responses are based on its current understanding and reserves the right to supplement and/or amend these responses.

INTERROGATORIES

1. Identify all current and former officers, directors, employees, agents, attorneys (whether in-house or outside attorneys), physicians, affiliated physicians agents, consultants or representatives of Rush Medical who has and/or had any involvement in the marketing, distribution, training, use and/or sale of the Accused Instruments, the Accused Techniques and/or the Accused Implants, and for each such person, describe in detail what involvement he or she has and/or had in the marketing, distribution, training, use and/or sale.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects to the extent that this interrogatory seeks privileged information. RUMC objects to the extent that this interrogatory seeks information not available to RUMC. RUMC objects to the extent that this interrogatory seeks to have RUMC speak for the actions or activities of other persons.

RUMC objects to the temporal scope of this interrogatory based on lack of relevance, overbreadth, and undue burden. Hudson has not established that it provided notice of its patents and/or established that it met the marking requirements of the Patent Act, foreclosing any damages prior to the initiation of this lawsuit. RUMC cannot be liable for infringement under 35 U.S.C. Section 271 (b) or (c) absent awareness of the patents, which Hudson has not established.

RUMC cannot be liable for damages for any period under 35 U.S.C. Section 287(c) especially for the '541 patent. This entire interrogatory is therefore irrelevant.

Subject to those objections, RUMC incorporates by reference its supplemental 26(a)(1) disclosure of persons with knowledge. RUMC also identifies the documents found at RUMC0002187-2654. RUMC reserves the right to supplement this response.

2. Separately, for each of the years 2002 forward, provide the following information: (a) state the number of surgeries, procedures and operations performed by, for or at Rush Medical using the Accused Techniques; (b) state the date and location of each such surgery, procedure and operation; (c) identify the physician(s) who performed the surgery, procedure or operation; (d) state the total revenues and profits (gross, operating and incremental) generated by Rush Medical for each such surgery, procedure and operation; (e) state the number of Accused Implants made, sold and implanted; and (f) state the total revenues and profits (gross, operating and incremental) generated by Rush Medical for each such implant.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects to the extent that this interrogatory seeks information not available to RUMC. RUMC objects to the extent that this interrogatory seeks to have RUMC speak for the actions or activities of other persons.

RUMC objects to the temporal scope of this interrogatory based on lack of relevance, overbreadth, and undue burden. Hudson has not established that it provided notice of its patents and/or established that it met the marking requirements of the Patent Act, foreclosing any damages prior to the initiation of this lawsuit. RUMC cannot be liable for infringement under 35 U.S.C. Section 271 (b) or (c) absent awareness of the patents, which Hudson has not established. Therefore, RUMC will not provide information for prior to the initiation of this lawsuit.

RUMC cannot be liable for damages for any period under 35 U.S.C. Section 287(c) especially for the '541 patent. This entire interrogatory is therefore irrelevant.

Moreover, since individual surgeons perform the surgeries independent of RUMC, the definitions supplied by Hudson are not specific enough to allow a determination of the surgeries for which Hudson is seeking discovery.

Subject to those objections, RUMC is investigating this interrogatory. RUMC reserves the right to supplement its response.

3. Separately, for each of the years 2002 forward, identify by trade name, model number, part number or other suitable designation each Accused Instrument in the possession, custody or control of Rush Medical and identify the source of each such Accused Instrument.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects to the extent that this interrogatory seeks information not available to RUMC. RUMC objects to the extent that this interrogatory seeks to have RUMC speak for the actions or activities of other persons.

RUMC objects to the temporal scope of this interrogatory based on lack of relevance, overbreadth, and undue burden. Hudson has not established that it provided notice of its patents and/or established that it met the marking requirements of the Patent Act, foreclosing any damages prior to the initiation of this lawsuit. RUMC cannot be liable for infringement under 35 U.S.C. Section 271 (b) or (c) absent awareness of the patents, which Hudson has not established.

RUMC cannot be liable for damages for any period under 35 U.S.C. Section 287(c) especially for the '541 patent. This entire interrogatory is therefore irrelevant.

Moreover, since individual surgeons perform the surgeries independent of RUMC, the definitions supplied by Hudson are not specific enough to allow a determination of the surgeries for which Hudson is seeking discovery.

Subject to those objections, RUMC identifies the documents found at RUMC0001553-1554, RUMC0001556-1565, and RUMC0001961-1964; and the spreadsheets found at RUMC0001609-1644, RUMC0001648-1927, RUMC0001935-1960, and RUMC0002655-4958. RUMC reserves the right to supplement this response.

4. Separately, for each of the years 2002 forward, identify each payment and/or other consideration received by Rush Medical from any third party, person or entity pertaining to the Accused Instruments, the Accused Implants and/or the Accused Techniques and separately state the amount, the date and the source of each payment.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects to the extent that this

interrogatory seeks information not available to RUMC. RUMC objects to the extent that this interrogatory seeks to have RUMC speak for the actions or activities of other persons.

RUMC objects to the temporal scope of this interrogatory based on lack of relevance, overbreadth, and undue burden. Hudson has not established that it provided notice of its patents and/or established that it met the marking requirements of the Patent Act, foreclosing any damages prior to the initiation of this lawsuit. RUMC cannot be liable for infringement under 35 U.S.C. Section 271 (b) or (c) absent awareness of the patents, which Hudson has not established.

RUMC cannot be liable for damages for any period under 35 U.S.C. Section 287(c). This entire interrogatory is therefore irrelevant.

Moreover, since individual surgeons perform the surgeries independent of RUMC, the definitions supplied by Hudson are not specific enough to allow a determination of the surgeries for which Hudson is seeking discovery.

RUMC charges for among other things operation room time, and that charge is not dependent on the specific type of knee replacement surgery performed.

Subject to those objections, RUMC identifies the documents found at RUMC0001553-1554, RUMC0001556-1565, and RUMC0001961-1964; and the spreadsheets found at RUMC0001609-1644, RUMC0001648-1927, RUMC0001935-1960, and RUMC0002655-4958. RUMC reserves the right to supplement this response.. RUMC reserves the right to supplement this response.

5. Separately, for each asserted claim of each patent in suit, explain why Rush Health contends that it has not infringed the claim. A complete answer to this interrogatory shall include at least the following information: an identification of each claim element and/or term that Rush Medical contends is not met by the Accused Instruments and/or the Accused Techniques literally or under the doctrine of equivalents; Rush Medical's contentions on the proper construction of each claim element and/or term that it contends is not met by the Accused Instruments and/or the Accused Techniques, with citations to intrinsic and extrinsic evidence supporting these contentions; an element-by-element comparison between each asserted claim of the patents in suit and the Accused Instruments and the Accused Techniques identifying each claim element and/or term that is not present in the Accused Instruments and/or the Accused Techniques and explaining why such element and/or term is not present; an explanation of why Rush Medical contends that it has not contributed to the infringement or actively induced infringement of any asserted claim; an identification of all documents and things supporting Rush Medical's answer to this interrogatory; and an identification of each person having information that supports Rush Medical's answer to this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects because this interrogatory is premature. The Court has established a schedule for claim construction. To the extent that this interrogatory seeks information outside of that schedule, RUMC objects.

RUMC is a related health care entity, as that term is defined in 35 U.S.C. Section 287(c). The Accused Techniques are medical activities under that same provision. Therefore, Hudson has no remedy against RUMC even if RUMC were to perform the Accused Techniques. Because there is no remedy, there is no case or controversy as between Hudson and RUMC relating to any alleged infringement by RUMC.

RUMC does not manufacture any Accused Instruments. RUMC therefore cannot be liable for direct or indirect infringement relating to the manufacture of Accused Instruments.

RUMC does not infringe the '272 patent either directly under 35 U.S.C. § 271(a) or indirectly under 35 U.S.C. § 271(b) or (c). RUMC is a medical hospital that makes available operating rooms and related operative services to physicians who have applied for and received

approval for clinical privileges at RUMC. In regards to knee replacement surgeries, RUMC does not employ the surgeons who perform the surgeries. Rather, the surgeons who conduct knee replacement surgeries at RUMC are independent of RUMC. Surgeons are not employees, but instead have applied for and been approved for clinical privileges to engage in knee replacement surgeries. The clinical privileges granted by RUMC are general and, in the context of this litigation, neither specifically authorize nor reference Accused Techniques. For example, RUMC approved Dr. Berger's application for clinical privileges related to orthopedic surgery. *RUMC0001991-2015*. Dr. Berger was (and is) approved for "Core Privileges" of the knee. *RUMC0001991*. Dr. Berger is also approved for "[u]se of external fixator device in leg and knee" and "[a]rthroplasty of the knee." *RUMC0002000*. As can be seen from the clinical privileges for Dr. Berger, RUMC's approvals are broad based and do not differentiate between the specific implants, devices, or techniques that Dr. Berger chooses to utilize in his surgeries. They cannot be the basis for an allegation of patent infringement that is specific to the actual implants, devices, or techniques utilized.

RUMC makes its operating rooms available to physicians who have staff privileges. The physician can reserve an operating room for a certain time period. RUMC has a "Preference Card" system. A sample preference card for Dr. Berger is seen at *RUMC0001543-1545*. RUMC is also producing other preference cards. The Preference Card lists the instruments, equipment and supplies that the physician wants to be present in the operating room at that certain time. RUMC does not choose the instruments, equipment and supplies to be used; rather, the physician makes that choice through his or her preference card. Indeed, a physician can opt as a preference Non-Zimmer medical equipment.

As can be seen in Dr. Berger's Preference Card, the procedure was an "Arthoplasty Total Knee." For that procedure, Dr. Berger requested, *inter alia*, the "MIS Tibial Cutting Jigs." This jig is provided in the form of a tray. The list of items found on that tray are found at *RUMC0001565*. A picture of the tray is found at *RUMC0001933*. As is readily apparent from the picture of the tray, the MIS Tibial Cutting Jig is provided for surgery in component parts that are not connected together. The physician during surgery is in charge of assembling the components how he/she sees fit for the particular surgery. RUMC has no input into that decision. Furthermore, RUMC does not own the MIS Tibial Cutting Jig. Rather, it is simply stored at RUMC on consignment.

Because the MIS Tibial Cutting Jig is in component parts, RUMC does not directly infringe claim 8 of the '272 patent, which is the only independent claim of that patent asserted against RUMC. *See Hudson's Response to RUMC's First Set of Interrogatories, Response to Interrogatory #2*. Claim 8 is limited to an apparatus that is fully assembled and connected together. Claim 8 is for an "apparatus" with, *inter alia*, "distal attachment means interconnected with the distal end of the alignment means"; "fixation means interconnected with the proximal end of the alignment means"; "cutting guide means interconnected with the alignment means"; and "milling means coacting with the cutting guide surfaces." The MIS Tibial Cutting Jig, or the provision of the MIS Tibial Cutting Jig to a physician for a surgery, cannot directly infringe claim 8 because the component parts are not connected in any manner.

A recent Federal Circuit decision, which is controlling authority for this patent infringement case, confirms that providing components which are separate cannot be direct infringement of a claim that requires a connection. *Cross Medical Prods., Inc. v. Medtronic*

Sofamor Danek, Inc., 424 F.3d 1293 (Fed. Cir. 2005). In *Cross Medical*, like in this case, the patent claim in question was for a medical device. The claim there required a "lower bone interface operatively joined to said bone segment." The Federal Circuit held that the term "joined" meant that "the interface and the bone must be brought together or connected to form a single unit." Similarly here, the claim language requiring the different components to be "interconnected" must mean that the different components be connected together.

In *Cross Medical*, there was a question as to whether surgeons would later connect the interface and the bone. The Federal Circuit held that inquiry completely irrelevant on the question of direct infringement, "Because Medtronic does not itself make an apparatus with the 'interface' portion in contact with bone, Medtronic does not directly infringe." *Id.* In *Cross Medical*, the patentee argued that there could be direct infringement because the device supplied by Medtronic was *capable* of being connected. The Federal Circuit rejected that argument because "the claim does not require that the interface be merely 'capable' of contacting bone; the claim has a structural limitation that the anchor seat be in contact with bone." Because for "infringe[ment] of an apparatus claim, the device must meet all of the structural limitations," the Federal Circuit held there was no direct infringement. *Id.* ("Cross Medical again fails to recognize that the limitation ... is absent until the screw and anchor are put in place during surgery.")

Similarly, in this case, claim 8 has the structural limitations that the different components be "interconnected." Claim 8 is limited to actual "interconnection;" there is nothing in the claim to suggest that being "merely capable" of interconnection is sufficient. Therefore, possessing or providing a surgical tray with unconnected components cannot directly infringe Claim 8 of the

'272 patent. For at least the same reasons, dependent claims 9-11 are similarly not directly infringed.

Even during actual surgeries (which RUMC does not control), there is no direct infringement by anyone of Claims 8-11 of the '272 patent. RUMC has been able to review videos of two surgeries provided by Hudson, and so RUMC provides its non-infringement contentions as to those videos.

RUMC has no involvement with the surgery depicted at H005466 (The "Tria Surgery"). The Tria surgery was not performed at an RUMC facility. The Tria surgery was not performed by a surgeon with privileges at RUMC. Therefore, RUMC cannot be liable for the Tria Surgery.

RUMC had no involvement with the specific choice of surgery depicted at H005467 (the "Berger Surgery"). It is the surgeon, not RUMC, who chooses the method of surgery and devices to be used at a surgery. Therefore, RUMC cannot be liable for the Berger Surgery.

In addition, the Tria and Berger Surgeries and the devices used therein do not infringe the '272 patent.

Claim 1 of the '272 patent requires, inter alia:

> "partially attaching the fixation head to the proximal tibia;
> aligning the alignment rod;
> completely attaching the fixation head to the proximal tibia;"

As such, Claim 1 requires a three-step process for attaching the fixation head to the proximal tibia, requiring: 1) partial attachment; 2) alignment; and 3) complete attachment. This is supported by the specification, at Col. 6, lines 9-20, which states that the fixation block is "preliminarily position over the proximal tibia, and one of the fixation pins is driven into the proximal tibia. Thereafter, the alignment rod is adjusted .... Upon proper alignment of the

alignment rod, the other fixation pin is driven into the proximal tibia to completely fix the fixation block...." However, in the Tria and Berger surgeries, a device is fixated to the tibia in one step. There is no partial attachment followed by a complete attachment in either surgery, as is required by claim 1.

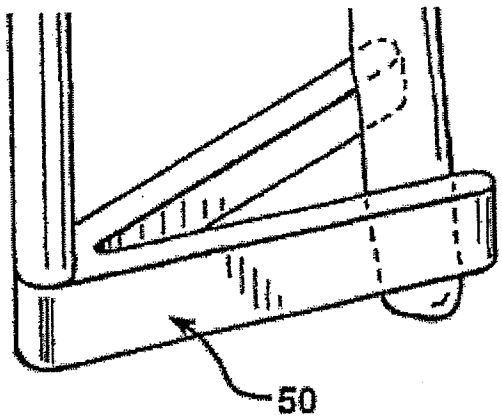
Claim 1 of the '272 patent additionally requires:

"interconnecting cutting guide clamps with the alignment rod;
positioning the cutting guide clamps about the proximal tibia"

The common, ordinary meaning for "about" is "all around; on all sides." The term "about" is not given a special definition in the '272 patent, and so it would take on that ordinary meaning. When used elsewhere in the specification, the term "about" uses this common definition of "all around." The patent specification provides that "the cutting guide clamps 10 pivot about the pivot shaft 76 of the cutting guide clamp linkage 70," '272 Patent, at col. 7, lines 17-19, referencing the fact that the guide clamps pivot all the way around the pivot shaft. The patent specification further provides that "[t]he milling bit may be spring loaded to increase resistance as it is plunged through the cutting guide to bias the bit against being plunged too far across the tibia to cause damage to the tissue about the tibia," again using about synonymously with all around. Looking elsewhere at the specification, it is clear that the term "about" means "all around; on all sides" or at the least "substantially all around; on at least three sides." Examples include placing a U-shaped device, which surrounds on at least three sides, "about" the tibia. '272 Patent, at col. 4, lines 25-26 ("a component that resembles a U-shaped device for placing about the tibia"); *Id.*, at col. 4, lines 30-31 ("component that resembles an adjustable, square, U-shaped device for placing about the tibia"). The ankle clamp shown in FIG. 6, which

is used to "firmly engage the ankle," *id.* at col. 5, lines 48-52, by attachment "about the ankle," *id.* at col. 6, lines 9-10, clamps around the ankle on three sides.

FIG. 6 (cutout)



The other Figures of the patent also support this reading of the term "about." FIG. 2 shows cutting guide clamps (10) that wrap most of the way around and grab the tibia.

FIG. 2 (cutout)

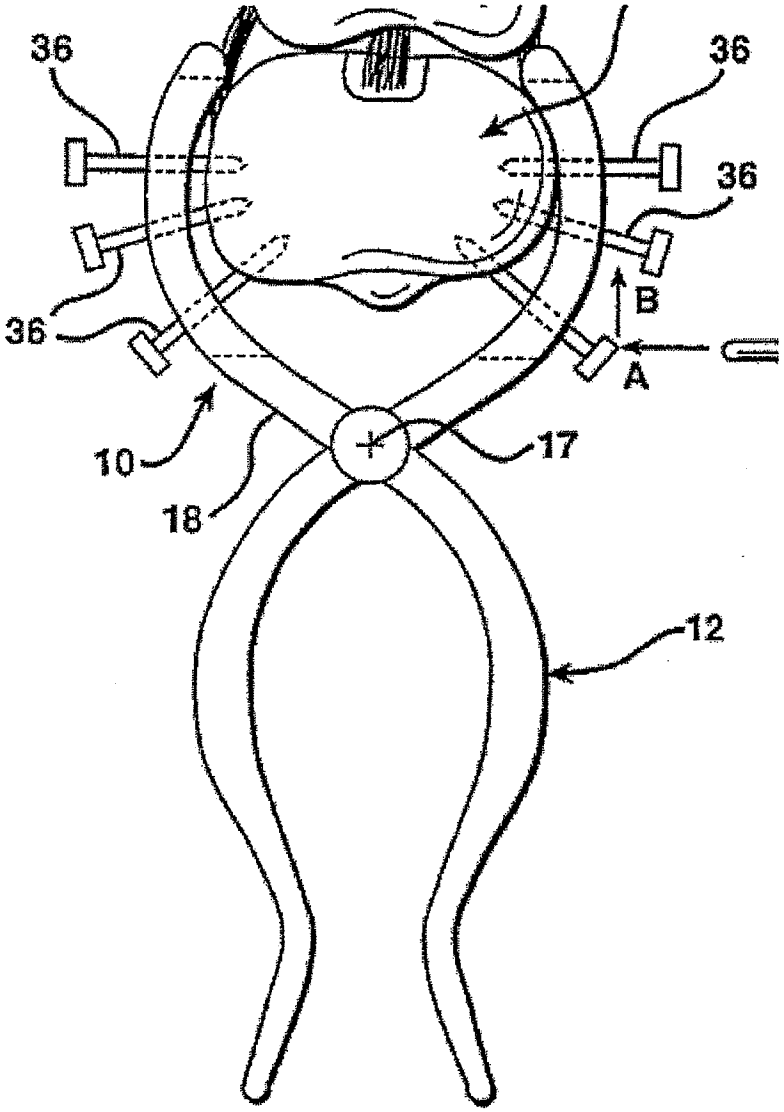


FIG. 5 similarly shows cutting guide clamps (10) that wrap around and grab the tibia on at least three sides.

FIG. 5

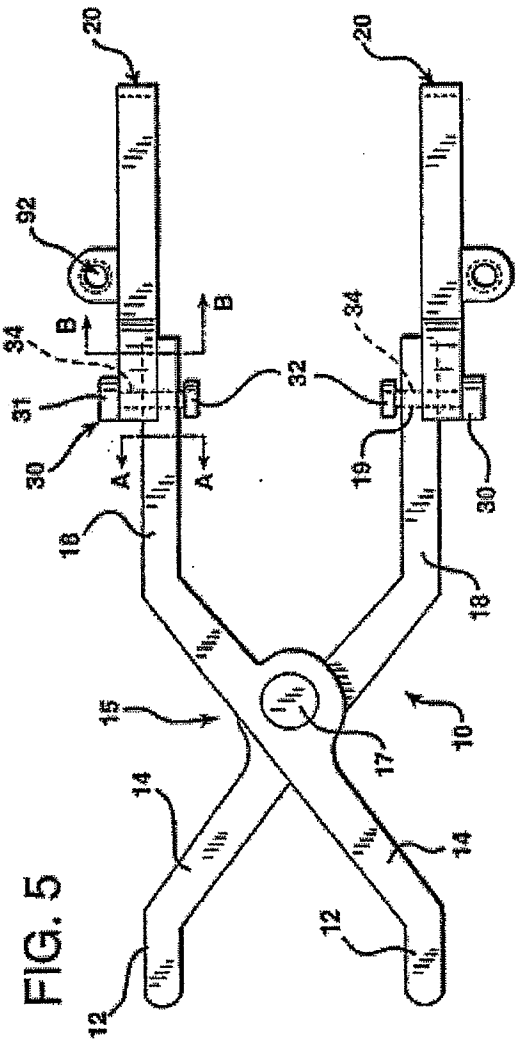


FIG. 5

Figure 6 also shows the cutting guide clamp surrounding at least three sides of the tibia.

FIG. 6

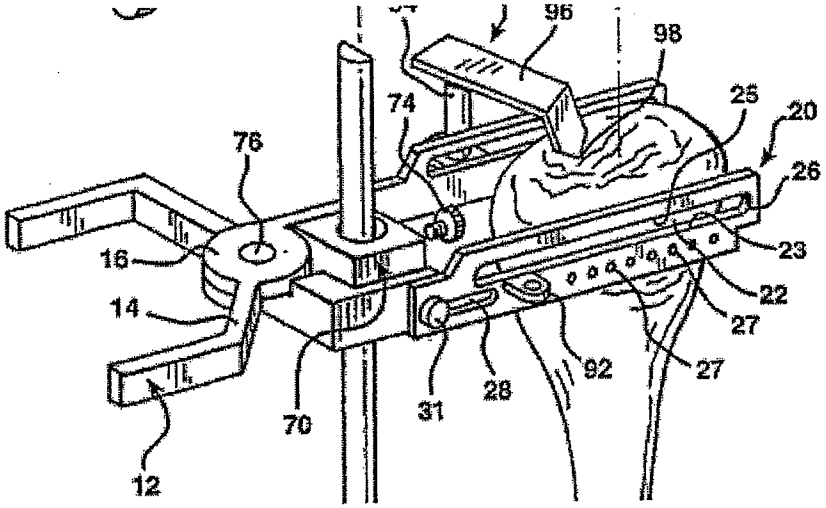
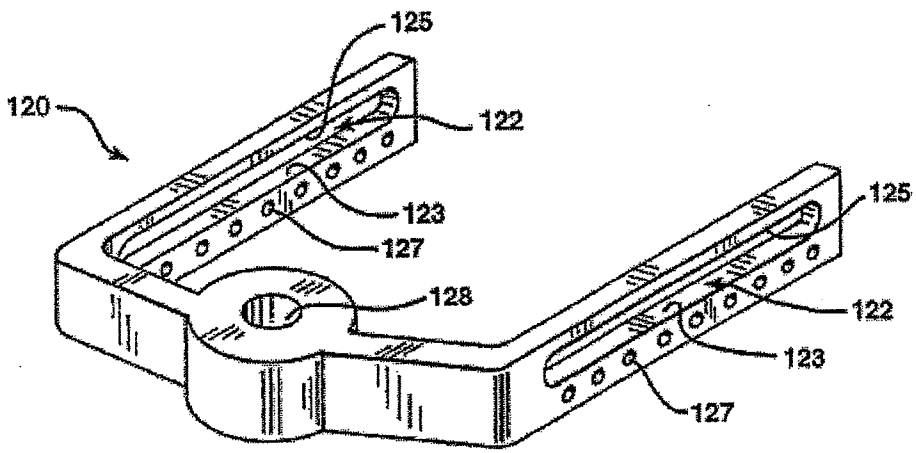


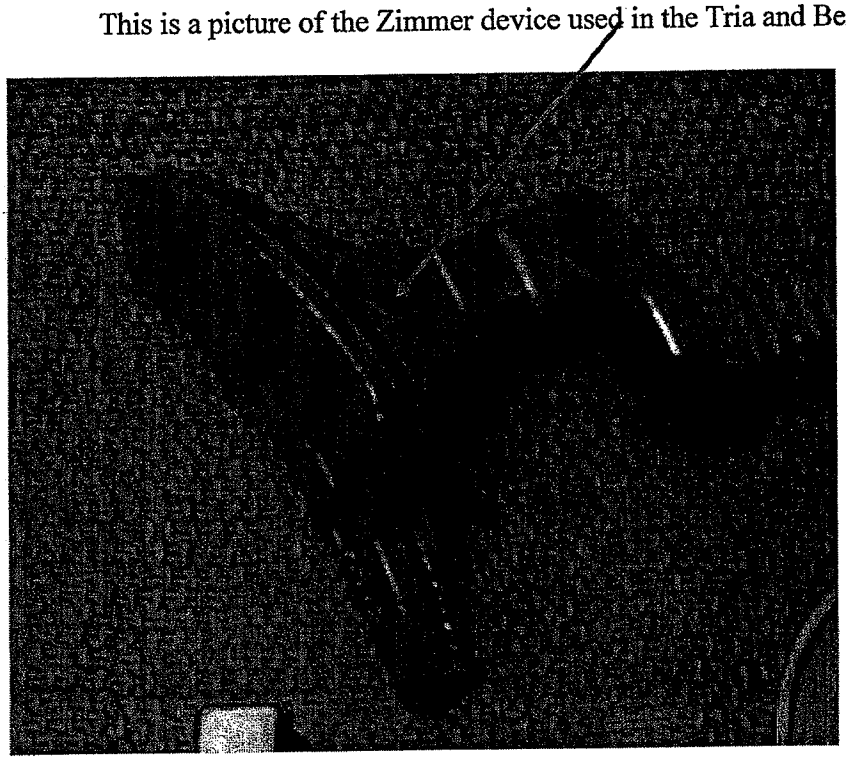
Figure 9 also shows the cutting guide clamp surrounding at least three sides of the tibia.

FIG. 9



Overall, the ordinary meaning of the term "about" as used in claim 1 means "around all sides" of the tibia, or at least substantially all sides of the tibia. This definition is also consistent with the rest of Claim 1, which requires "cutting guide clamps" to be positioned "about" the tibia. The common meaning of the term clamp is consistent with what is seen in Figure 2 and Figure 5, which show what are referred to in the patent as "cutting guide clamps 10." Clamps denote a gripping object that surrounds the gripped object on several sides to create a tight and secure fit. Therefore, the plain language of claim 1, as supported in the specification, requires the cutting guide to be a clamp that is securely positioned around all or at least substantially all sides of the tibia.

This is a picture of the Zimmer device used in the Tria and Berger Surgeries:



As can be readily seen, the Zimmer device is not a clamp and it is not positioned "about" the tibia to grab it securely on all or at least three sides of the tibia. Rather, the Zimmer device is slightly arcuate and rests on one side of the tibia. The Zimmer device does not clamp on the tibia, but rather is attached with one screw which is drilled through the hole shown with an arrow above. Because the surgeries employing the Zimmer device do not include "cutting guide clamps" and further do not involve positioning those clamps "about" the tibia, there is no infringement of claim 1.

Claim 1 of the '272 patent additionally requires:

"removing the fixation head from the tibia; and
cutting the proximal tibia with a milling bit."

From its plain language, claim 1 requires that the fixation head be removed from the tibia

prior to cutting the proximal tibia with a milling bit. The claim thus requires a separate "fixation head" that is removed from the surgery as one of its claimed steps. However, in the Zimmer surgeries, there is no removal of any separate portion of the device. The entire device is removed all together at one time.

Furthermore, the logical requirement of claim 1 is that a fixation head must be removed before the cutting of the tibia. The order of the events is a required element of the claim. To construe the claim otherwise would completely eviscerate the claim element. In every surgery, the device fixated to the tibia is removed at some point – the surgical device is not an implant and is not left in the patient when the surgery is over. The allegedly novel feature of claim 1 must be that the fixation head is removed before cutting. However, in the Zimmer surgeries there is no portion of the device that is removed before cutting the tibia. Because this claimed element of the Hudson procedure is not present in the Zimmer procedures, there can be no infringement.

For at least the same reasons, dependent claims 2, 3, 4 and 5, which include all of the limitations of claim 1, are not infringed.

RUMC does not infringe independent claim 6 of the '272 patent. Claim 6 of the '272 patent requires, inter alia:

"cutting guide means comprising two members in opposing relationship"

The United States Patent and Trademark Office originally rejected many of Hudson's patent claims because they were already known to the public and disclosed in prior art references. In an attempt to avoid those references, Hudson amended many of its claims to specifically require that the cutting guide means be in "opposing relationship." For example, in its

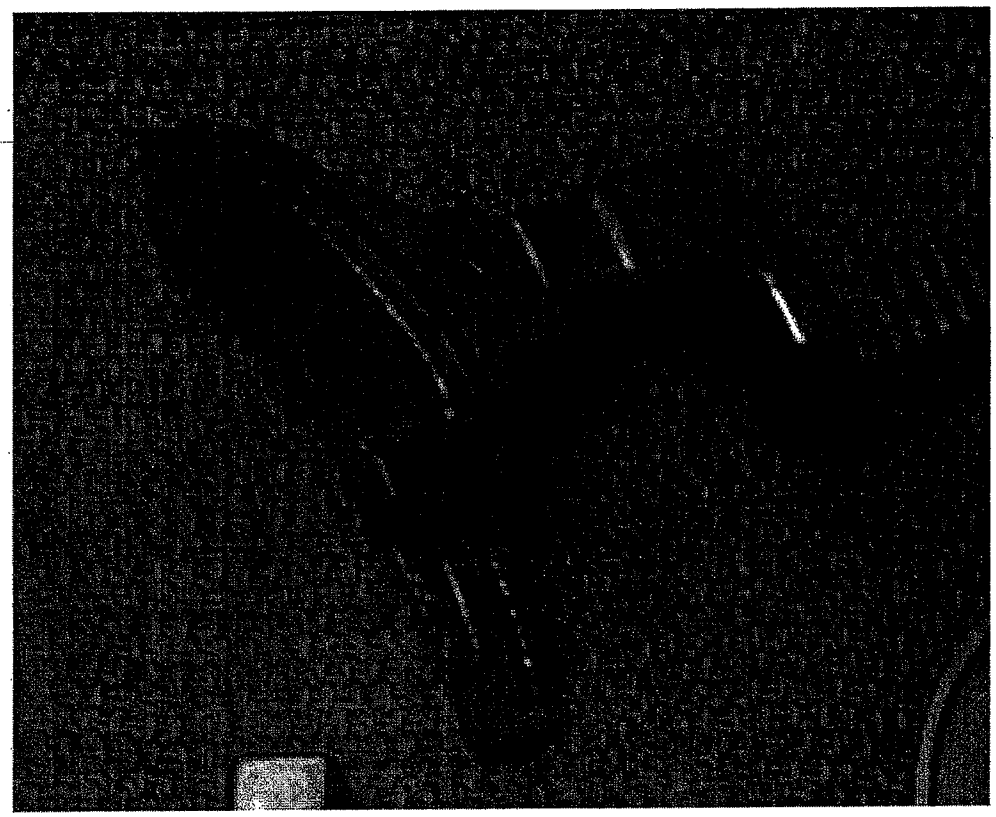
amendment of August 1, 1996, Hudson remarked:

> "Applicant respectfully submits that the pending claims overcome the reference relied on in the Office Action for rejection of the claims. With particularity, Applicant has re-written old claim 1 as new independent claim 20, and has added the limitation that the cutting guide means comprises: '... cutting guides **positioned in opposing relation** across a tibia, the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to a tibia.' Applicant has likewise included a similar limitation in new claim 29 as follows: '... positioning the cutting guide clamps in opposing relation across the proximal tibia."

8/1/19966 Office Action, at H000720-721. Hudson went on to rely on this specific "opposing relation" language as the basis to distinguish its claimed invention as different from that described in U.S. Pat. No. 4,938,762 to Wehrli. Similarly, in its January 15, 1997, Office Action, Hudson again relied on the cutting guide means being on opposing sides of the tibia to try to distinguish the prior art. *1/15/1997*, at H000735-737. Hudson specifically amended its claims to include the limitation of the cutting guides being on "opposing sides of the tibia." *Id.*, at H000733 (the underlining of those words in the amendment signifies that those words were being added). The importance of the term "opposing" is further demonstrated in the Notice of Allowability, where the Examiner for the U.S.P.T.O. required that the term "opposing" be added before allowing the claim to be included in a patent. *1/15/1997 Notice of Allowability*, at H000740. In sum, the claimed language of cutting guide means being in "opposed relation" is of critical importance to the '272 patent claims.

The device used in the Tria and Berger surgeries is again shown below.

ZIMMER DEVICE



The above pictured device is the only device used in the cutting operation. There is therefore no "two members." Moreover, there are not two members "in opposing relationship."

Claim 6 further requires that the cutting guide means have:

"entrance areas comprising upturned slot areas communicating with the cutting guide slots for receiving a milling bit ...."

As can be seen in the picture of the Zimmer device above, there is no upturned slot area. The Zimmer device therefore does not infringe claim 6.

Claim 6 further requires:

"the cutting guide means including hand grips, mating cross bars having pivot apertures and clamp members, the cutting guide means adjustably interconnected with the clamp members ...."

As can be seen in the picture of the Zimmer device above, there are no hand grips or mating cross bars. Similar to the method claims, this is because the Hudson claimed device focuses on clamps, which the Zimmer device does not have.

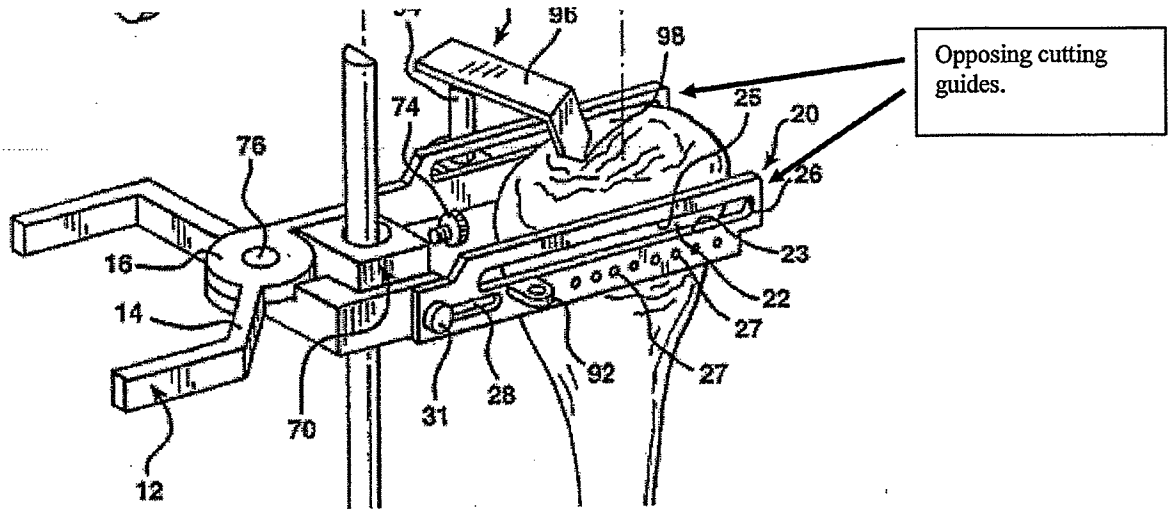
RUMC does not infringe claim 7, which is dependent on claim 6, for at least the same reasons.

RUMC does not infringe independent claim 8 of the '272 patent. Like claim 6 described *supra*, claim 8 of the '272 patent requires that the cutting guide be on opposing sides of the tibia. This is seen in the claim language that again requires the cutting guide to be positioned on opposing sides of the tibia. Claim 8 specifically requires:

> "cutting guides positionable in opposing relation along sides of the tibia, the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia ...."

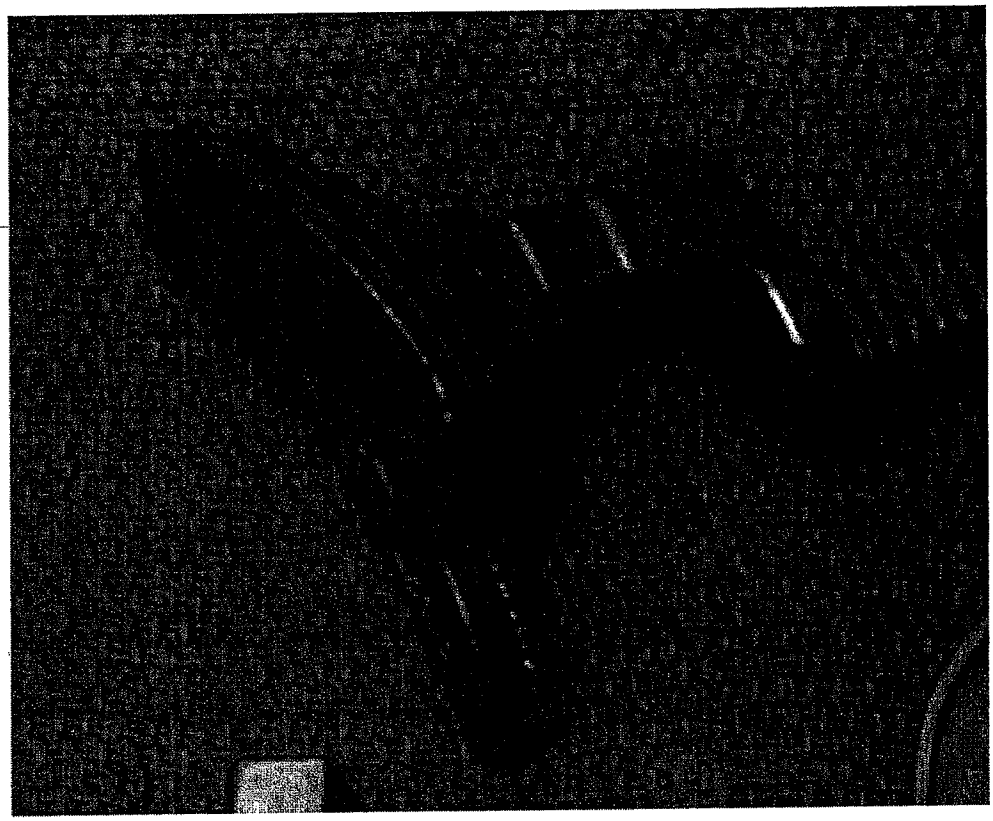
This claim describes cutting guide means that are on multiple sides of the tibia at the same time, such as seen in Figure 6 of the '272 patent:

FIGURE 6 of the '272 Patent



As is clearly shown in the figure, the opposing cutting guides are on opposite sides of the tibia and clamp around the tibia. Further, the fact that cutting guides according to the '272 patent were opposing was **critical** to patentability – as described *supra* in regards to claim 6, they were added by amendment to avoid the prior art and were required by the Patent and Trademark Office as a condition to issuing the patent.

The apparatus used in the Tria and Berger surgeries does not employ opposed cutting guides. Here is a picture of the only device used in those surgeries:



This device is attached to only one side of the tibia during the surgery. There is therefore no infringement of claim 8 of the '272 patent.

The non-infringement of claim 8 is further confirmed by Hudson's claim charts. Those claim charts conspicuously show that cutting guides in opposing relation are not used during the accused knee replacement surgeries, as they include pictures of the actual tibial cutting apparatus that do not have such opposing guides. Indeed, the claim charts specifically note that such opposing parts are "not shown." They are not shown because they are not actually utilized. It is axiomatic that an accused apparatus must have *all* of the elements of a claim, yet Hudson admits in its claim charts that the devices used in the surgeries they rely on to show infringement do not have all the required elements. A finding of non-infringement is therefore mandated.

For at least the same reasons, there is no infringement of dependent claims 9, 10, 11, 12, 13, 14 and 15.

RUMC does not infringe claim 16 of the '272 patent. Like the other claims described *supra*, claim 16 requires the cutting guide have members that are on opposing sides of the tibia. Specifically, claim 16 provides, *inter alia*:

> "positioning the cutting guide means in opposing relation along sides of the proximal tibia; securing the cutting guide means to opposing sides of the tibia ...."

For the same reasons described above in relation to claims 1, 6 and 8, this claim language requires that the cutting guides be in opposing relation and was required for patentability by the U.S.P.T.O. The Zimmer device used in the Tria and Berger surgeries is only attached to one side of the tibia. Therefore, there is no infringement of claim 16.

For at least the same reasons, there is no infringement of dependent claims 17, 18 or 19.

Hudson has not shown that RUMC was aware of the patents in suit prior to the initiation of the instant action. Hudson has not shown that it provided notice and/or marking under the patent statute. Therefore, RUMC cannot be liable for any damages accruing from before the initiation of this litigation.

For the time period before the initiation of this lawsuit, RUMC cannot be liable for contributory or inducing infringement because it has not been shown that RUMC was aware of the patents in suit.

Furthermore, for all time periods, RUMC cannot be liable for contributory or inducing infringement because there are substantial non-infringing uses of the components of the tibial

tray provided to the surgeon for surgery. As shown above, actual surgeries by Drs. Tria and Berger do not infringe because they do not use an apparatus with more than one cutting guide in opposing relation as required by all claims of the '272 patent including the asserted claim 8. Furthermore, it appears that Zimmer's recommended tray only includes one device for cutting the tibia. *See, e.g.*, EZHX000022; EZHX00618-0619.

RUMC reserves the right to supplement this response.

6. Separately for each asserted claim of each patent in suit that Rush Medical contends is invalid for failure to comply with the requirements of 35 U.S.C. § 102, explain the factual and legal basis for the contention. A complete answer to this interrogatory shall include at least the following information: an identification of each item of alleged prior art; an explanation of why the item is prior art to any asserted claim of a patent in suit; an element-by-element application of each item of alleged prior art to each asserted claim; an identification of all documents and things supporting Rush Medical's answer to this interrogatory; and an identification of each person having information that supports Rush Medical's answer to this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects based on privilege. RUMC is investigating this interrogatory. RUMC reserves the right to supplement this response.

7. Separately for each asserted claim of each patent in suit that Rush Health contends is invalid for failure to comply with the requirements of 35 U.S.C. § 103, explain the factual and

legal basis for the contention. A complete answer to this interrogatory shall include at least the following information: an identification of each item of alleged prior art, including an explanation of why the item is prior art to any asserted claim of a patent in suit; Rush Medical's contentions on the level of ordinary skill in the art at the time the inventions recited in the claims were made; Rush Medical's contentions on the scope and content of the prior art and the differences between the prior art and each asserted claim; where Rush Medical relies on combinations of items of alleged prior art, an identification of each combination (including the specific portions of the items of alleged prior art that are being combined) and an explanation of why a person skilled in the art would have made the combination at the time the patented inventions were made; Rush Medical's contentions on the presence or absence of objective indicia of non-obviousness such as commercial success, copying, long-standing problem or need, failure of others, unexpected results and skepticism regarding the patented inventions; an identification of all documents and things supporting Rush Medical's answer to this interrogatory; and an identification of each person having information that supports Rush Medical's answer to this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects based on privilege. RUMC is investigating this interrogatory. RUMC reserves the right to supplement this response.

8. Identify and describe the date(s) on which and the circumstances under which Rush Medical first became aware of U.S. Patent Application No. 08/300,379; U.S. Patent No. 5,514,319; U.S. Patent Application No. 08/342,143; U.S. Patent No. 5,597,379; U.S. Patent Application No. 08/479,363; U.S. Patent No. 5,643,272; U.S. Patent Application No. 08/603,582; U.S. Patent No. 5,810,827; U.S. Patent Application No. 10/756,817; and U.S. Patent No. 7,344,541. A complete answer to this interrogatory shall include an identification of documents and things pertaining to the subject matter of the interrogatory and an identification of all persons having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects based on privilege. Subject to those objections, RUMC had no awareness of the patents listed until the initiation of

this lawsuit. RUMC reserves the right to supplement this response.

9. Describe any action, analysis or opinion requested, considered, provided or undertaken by or for Rush Medical pertaining to the patents in suit, including, but not limited to, any attempt to avoid infringement of or design around the patents in suit. A complete answer to this interrogatory shall include at least the following information: a description of the action, analysis or opinion; a description of the results, if any, of the action, analysis or opinion; an identification of the dates on which any such action, analysis or opinion was requested, considered, provided or undertaken; an identification of all documents and things pertaining to the subject matter of this interrogatory; and an identification of each person having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects based on privilege. Subject to those objections, RUMC had none prior to the initiation of this suit. RUMC reserves the right to supplement this response.

10. Separately, for each patent in suit, state Rush Medical's contentions on the issue of the amount of damages for infringement in the event the patent is held valid, enforceable and infringed, including the amount of such damages and the method of calculation. A complete answer to this interrogatory shall include at least the following information: an identification of all factors (including but not limited to factors set forth in the Georgia Pacific decision) that Rush Medical contends are relevant to the determination of a reasonable royalty in a hypothetical negotiation between Rush Medical and Hudson Surgical for a license under the patent; a description of how each such factor applies to the hypothetical negotiation; the particular terms Rush Medical would have proposed and/or accepted in the hypothetical negotiation; the amount Rush Medical contends to be a reasonable royalty; an identification of all documents and things pertaining to the subject matter of this interrogatory; and an identification of each person having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects because this interrogatory is overbroad and unduly burdensome because it purports to require RUMC to provide information from before the filing of this lawsuit. RUMC objects based on lack of relevance. RUMC objects because this interrogatory is premature. Hudson is the plaintiff in this action and has alleged infringement. However, Hudson has to date not adequately identified the instruments of Zimmer for which it is alleging infringement. It is premature for RUMC to set forth damages positions when Hudson has not yet clearly identified what it alleges is infringing.

RUMC does not itself perform any of the Accused Techniques. Therefore, RUMC cannot be liable for direct infringement.

RUMC is a related health care entity, as that term is defined in 35 U.S.C. Section 287(c). The Accused Techniques are medical activities under that same provision. Therefore, there is no remedy against RUMC even if it were to perform the Accused Techniques. Because there is no remedy, there is no case or controversy as between Hudson and RUMC relating to any alleged infringement by RUMC. There are also no damages for any period.

Hudson has not shown that RUMC was aware of the patents in suit prior to the initiation of the instant action. Hudson has not shown that it provided notice and/or marking under the patent statute. Therefore, RUMC cannot be liable for any damages stemming from before the initiation of this litigation. RUMC cannot be liable for contributory or inducing infringement because it has not been shown that RUMC was aware of the patents in suit. Therefore, the issue of damages is not relevant for any time period before the initiation of this lawsuit.

RUMC does not participate in the decision-making as to the procedure and/or devices

that are used during a specific knee surgery. Individual surgeons perform the surgeries independent of RUMC. RUMC therefore cannot be liable for any type of infringement or responsible for damages. Subject to these objections, RUMC reserves the right to supplement this response.

11. Identify each person Rush Medical expects to call as a witness (including both fact and expert witnesses) at any hearing or trial in this suit. For each such person identified, state the subject matter of the testimony to be provided and identify all documents and persons consulted or to be consulted by each witness in preparation for his or her testimony.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects because this interrogatory is premature. Subject to those objections, RUMC will identify any person as required by Federal Rule of Civil Procedure 26 or the Court's scheduling order. RUMC reserves the right to supplement this response.

12. Identify each patent or patent application filed, owned, controlled or licensed by or to Rush Medical that describes, covers or otherwise pertains to any Accused Instrument, any Accused Technique and/or any Accused Implant.

RESPONSE:

RUMC incorporates all of its objections herein. Subject to those objections, RUMC has not filed or licensed any such patent or patent application. RUMC does not own or control any such patent or patent application. RUMC reserves the right to supplement this response.

13. Identify and describe each contact, communication, contract, agreement, arrangement or understanding (including but not limited to indemnification agreements and joint defense agreements) between Rush Medical and any third party, person or entity regarding Hudson Surgical, Hudson Surgical's patent rights, the patents in suit and/or this lawsuit, and identify each person having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC objects based on privilege. RUMC objects that the term third party is vague and lacks particularity. RUMC objects to this interrogatory as vague and overbroad, especially in regards to the meaning of "regarding Hudson Surgical, Hudson Surgical's patent rights, the patents in suit and/or this lawsuit." Subject to those objections and without making any statement as to whether these agreements are "regarding Hudson Surgical, Hudson Surgical's patent rights, the patents in suit and/or this lawsuit," RUMC identifies the agreements Bates-labeled RUMC0001312-1542. The agreements speak for themselves, and Hudson can determine the answer to this interrogatory by examining the agreements. RUMC reserves the right to supplement this response.

14. Identify and describe each contact, communication, contract, agreement, arrangement or understanding between Rush Medical and any third party, person or entity (including, but not limited to, Zimmer Holdings, Inc., Zimmer, Inc., hospitals, health care providers, medical facilities and physicians) pertaining to the Accused Instruments, the Accused Techniques and/or the Accused Implants and identify each person having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC incorporates its response to Interrogatory No. 13 herein. RUMC reserves the right to supplement this response.

15. Describe the dates, locations and content [sic] any training pertaining to the Accused Instruments, the Accused Techniques and/or the Accused Implants provided by, for or at Rush Medical, and identify all documents and things pertaining to the subject matter of this interrogatory and each person having information pertaining to the subject matter of this interrogatory.

RESPONSE:

RUMC incorporates all of its objections herein. RUMC is investigating this interrogatory. RUMC reserves the right to supplement this response.

Dated: August 15, 2008.

For the objections,

Robert B. Breisblatt
Sheldon T. Zenner
Brian J. Sodikoff
Thomas J. Maas
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was served on the following via U.S. Mail, with a courtesy copy via email, on:

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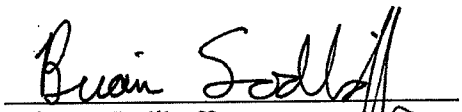

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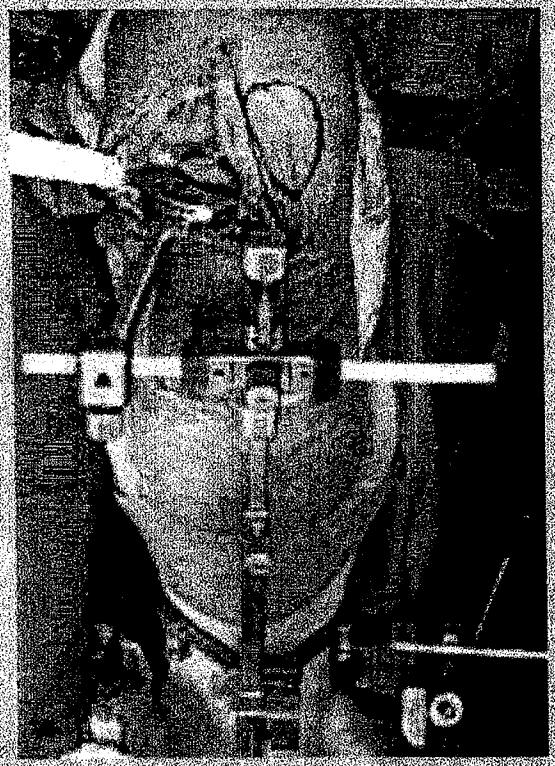
EXHIBIT G/PART 1

Preliminary Chart Summarizing Infringement of Claims 8-11 of U.S. Patent No. 5,643,272 by Zimmer's "Minimally Invasive Solutions (MIS) Quad-Sparing TKA" Instruments



US005643272A

United States Patent [19]
Haines et al.

[11] Patent Number: 5,643,272
[45] Date of Patent: Jul. 1, 1997

[54] METHOD AND APPARATUS FOR TIBIAL RESECTION

[75] Inventors: Timothy G. Haines, Stewartsville; David B. Goldstein, Weehawken, both of N.J.

[73] Assignee: Biomet Surgical Design, Inc., Rutherford, N.J.

[21] Appl. No.: 479,363

[22] Filed: Jun. 7, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 300,279, Sep. 2, 1994, Pat. No. 5,514,139, and Ser. No. 342,143, Nov. 18, 1994, Pat. No. 5,597,379, which is a continuation-in-part of Ser. No. 300,279.

[51] Int. Cl.[6] A61B 17/56
[52] U.S. Cl. 606/88; 606/88
[58] Field of Search 606/88, 87, 86, 606/80, 82, 96

[56] References Cited

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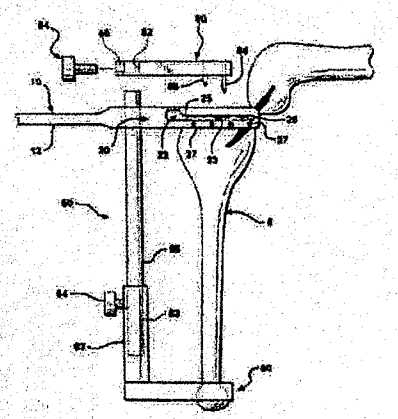
5,342,368	8/1994	Petersen	606/88

Primary Examiner—Guy V. Tucker
Attorney, Agent, or Firm—Pitzis & Nussbaum

[57] ABSTRACT

A method an apparatus for resecting a proximal tibia during a knee replacement operation is provided. The apparatus includes an ankle clamp, an alignment rod, a fixation head, cutting guide clamps having cutting guide slots therein, and a milling bit. The method includes the steps of attaching the ankle clamp about the ankle, interconnecting the distal end of the alignment rod with the ankle clamp, interconnecting the fixation head with the proximal end of the alignment rod, partially attaching the fixation head to the proximal tibia, aligning the alignment rod, completely attaching the fixation head to the proximal tibia, interconnecting the cutting guide clamps with the alignment rod, positioning the cutting guide clamps about the proximal tibia, securing the cutting guide clamps to the tibia at a proper location, removing the fixation head, placing the milling bit within the cutting guide slots, and cutting the proximal tibia with the milling bit.

19 Claims, 3 Drawing Sheets



Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,

the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,

the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia, and

milling means for cutting the tibia,

the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guide means comprises a "LEFT" tibial cutting guide and a "RIGHT" tibial cutting guide. The cutting guides are positionable in opposing relation along the sides of the tibia. Additionally, a LEFT Medial cutting guide is also a RIGHT Lateral Cutting Guide.

Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,
the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,
the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

milling means for cutting the tibia,
the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guides in Zimmer's MIS equipment are positionable along medial and lateral sides of a tibia.

The *MIS Quad-Sparing* TKA instrument sets are designed to accommodate exposure from the medial side of the joint and for a right or left limb. Appropriate adjustments must be made, including the use of different instruments and attending an advanced training course prior to using a lateral approach.

EXHIBIT G/PART 2

Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

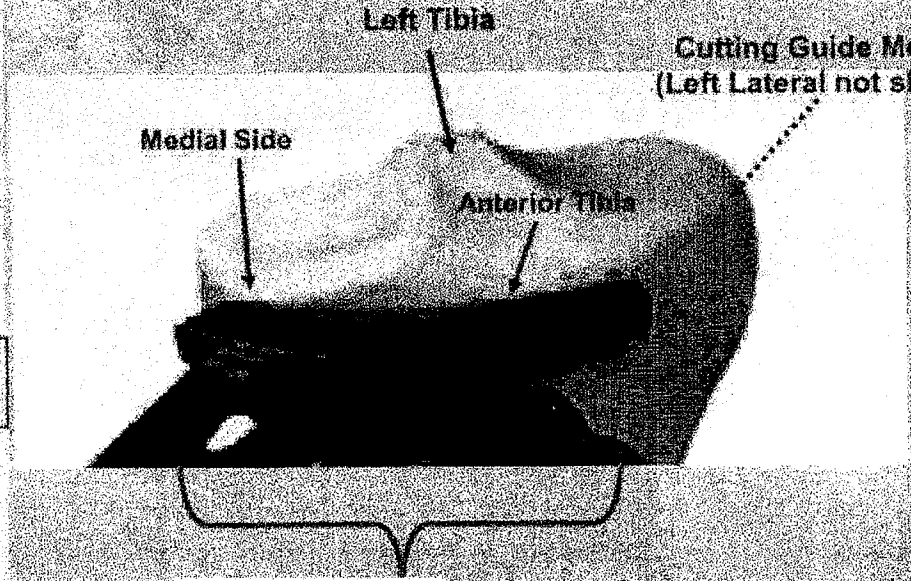
fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,
the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,
the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

milling means for cutting the tibia,
the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guide means comprises a "LEFT" tibial cutting guide and a "RIGHT" tibial cutting guide. The cutting guides are positionable in opposing relation along the sides of the tibia. Additionally, a LEFT Medial cutting guide is also a RIGHT Lateral Cutting Guide.

"With the Tibial Cut Guide flush against the anteromedial edge of the tibia..." [P 11, Col 3].



Insert the correct right or left Tibial Cut Guide into the adjustable rod and rotate

Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,

the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,

the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

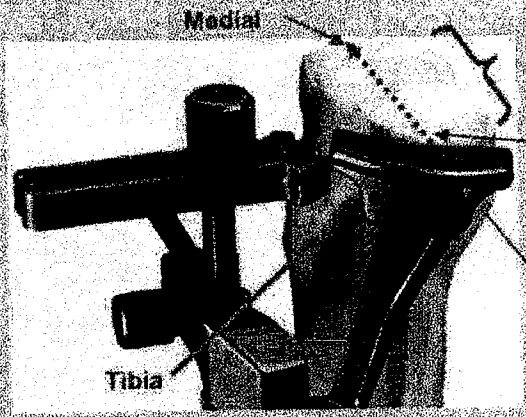
milling means for cutting the tibia,

the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guide means comprises a "LEFT" tibial cutting guide and a "RIGHT" tibial cutting guide. The cutting guides are positionable in opposing relation along the sides of the tibia. Additionally, a LEFT Medial cutting guide is also a RIGHT Lateral Cutting Guide.

Using the lateral incision, the lateral tibial plateau is first removed and then the medial tibial plateau is resected. [P231, Col 1]

Figure 3 The proximal tibial cut is made using the medial-based cutting slot on the tibial cutting guide for the medial incision and the lateral-based slot for the lateral incision.



Minimally Invasive Total Knee Replacement Surgery with a Lateral Approach, E. Marlowe Goble, MD,* and Steven M. Kane, MD†, Semin Arthro 16:227-234 © 2005

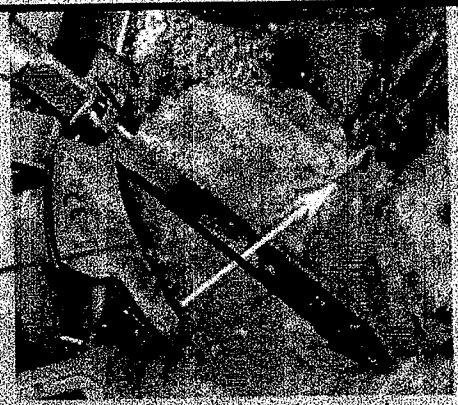


Figure 7 . . . (B) The white arrows shows the previous anteroposterior cut and the *black arrow traces the oblique cut from medial to lateral* . . .

Shin, Alan, Tria, Oper Tech Orthop 16:170-176, Minimally Invasive Quadriceps-Sparing Posterior Stabilized Total Knee Arthroplasty

Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,

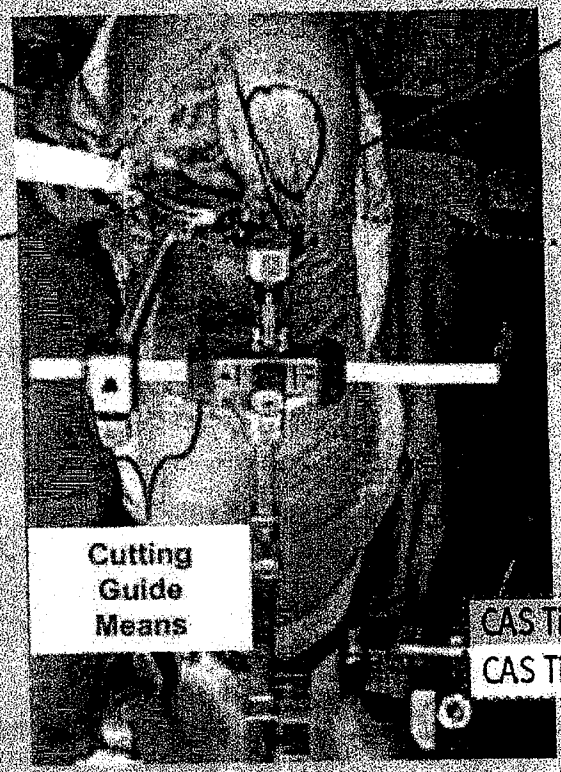
the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,

the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

milling means for cutting the tibia,

the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guide means comprises a "LEFT" tibial cutting guide and a "RIGHT" tibial cutting guide. The cutting guides are positionable in opposing relation along the sides of the tibia. Additionally, a LEFT Medial cutting guide is also a RIGHT Lateral Cutting Guide.



AAOS DVD; Electromagnetic Quad Sparing Surgical Technique

Claim 8 of the '272 Patent

8. An apparatus for resecting a proximal human tibia comprising:

alignment means having proximal and distal ends;

distal attachment means for attaching to the tibia, the distal attachment means interconnected with the distal end of the alignment means;

fixation means for attachment to the proximal tibia, the fixation means interconnected with the proximal end of the alignment means for aligning the alignment means;

cutting guide means interconnected with the alignment means,

the cutting guide means comprising cutting guides positionable in opposing relation along sides of the tibia,

the cutting guides including cutting guide surfaces and fixation means for affixing the opposing cutting guides to opposing sides of the tibia; and

milling means for cutting the tibia,

the milling means coacting with the cutting guide surfaces of the cutting guide means for resecting the tibia.

The cutting guide means comprises a "LEFT" tibial cutting guide and a "RIGHT" tibial cutting guide. The cutting guides are positionable in opposing relation along the sides of the tibia. Additionally, a LEFT Medial cutting guide is also a RIGHT Lateral Cutting Guide.

NexGen® Complete Knee Solution MIS Quad-Sparing™ Instrumentation

http://www.zimmer.com/ctl?template=MP&ep=global&notice=1&id=9403 (2 of 7)8/13/2007 9:35:25 AM

Successful total knee arthroplasty depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability.

The *NexGen* Complete Knee Solution System and the *Zimmer® MIS Quad-Sparing* Instruments are designed to help the surgeon accomplish these goals by combining optimal alignment accuracy with an innovative technique that helps avoid any muscle disruption, tendon dissection or patellar dislocation. Furthermore, the *MIS Quad-Sparing* Instrumentation is designed to:

- Facilitate a smaller incision technique thereby reducing tissue trauma and improving early return of range of motion
- Approach bone resection from the medial or lateral side.
- Allow adjustment and control of alignment prior to performing any bone cuts.
- Shorten hospital length of stay and with appropriate peri-operative management, some patients can go home the day of surgery

Zimmer Website

EXHIBIT H

REDACTED CONFIDENTIAL DOCUMENT

EXHIBIT I

RUSH UNIVERSITY MEDICAL CENTER

HOME | FOR PHYSICIANS | RUSH UNIVERSITY

SEARCH GO

ABOUT RUSH | CONTACT US | MAKE APPOINTMENT | NEWSLETTER SIGN-UP | INFORMACION DE SALUD

- FIND A DOCTOR
- PATIENT & VISITOR SERVICES
- HEALTH INFORMATION
- CLINICAL SERVICES
- EVENTS & CLASSES
- RUSH NEWS ROOM
- CLINICAL TRIALS
- RESEARCH AT RUSH
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FIND A DOCTOR

Physician Directory

Use the form below to search for a physician matching your search criteria.

PLEASE NOTE: All physicians featured in Find A Doctor are on the medical faculty of Rush University Medical Center. Some of the physicians featured are in private practice and, as independent practitioners, are not agents or employees of Rush University Medical Center.

Search by keyword

Keyword:

Or, search using the fields below.
Use one field at a time for best results.

Last Name:

First Name:

Specialty: Pull down menu to select options

City: Pull down menu to select options

Practice Emphasis: Pull down menu to select options

Special Interests: Pull down menu to select options

Special Procedures: Pull down menu to select options

Research Interests: Pull down menu to select options

Languages: Pull down menu to select options

Gender: Pull down menu to select options

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EXHIBIT J

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THOMAS J. MAAS
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July 25, 2008

Via E-Mail

Mr. David J. Sheikh
Niro, Scavone, Haller & Niro
181 W. Madison Street, Suite 4600
Chicago, IL 60602

Re: Hudson Surgical, Inc. v. Zimmer Holdings, Inc. et al.

Dear David,

This letter speaks to the status of discovery in this action and further provides responses to the issues raised in your letter of July 18, 2008. In your letter, you state "RUMC must participate in the discovery process and comply with the Federal Rules of Civil Procedure," which could be read as suggesting that Rush has not done so to date. However, as detailed below, it is in fact Hudson who was to date failed to engage in the discovery process. In fact, while Rush has produced a number of internal documents responsive to Hudson's requests, Hudson has not produced a single internal document.

Rush served its first discovery requests and interrogatories on Hudson on June 9, nearly seven weeks ago. As detailed below, these requests sought documents relevant to a number of claims and defenses. However, in response, Hudson only provided publicly available documents, mostly from the internet. It is simply not fathomable that Hudson has absolutely no internal documents relevant to the issues of this litigation, and yet Hudson has not produced any such documents.

It is not proper for Hudson to interpret the Federal Rules as imposing substantially different burdens on each party. Rush has already imposed on personnel – who are busy providing medical care – to produce documents responsive to Hudson's requests, yet Hudson just keeps seeking to impose more burdens on Rush. At the same time, Hudson has thus far failed to put any effort into producing its own documents. Such a disparity should not continue.

We therefore ask that Hudson demonstrate good faith, cooperation, and diligence in fulfilling its own discovery obligations. To this end, we have identified areas where Hudson's disclosures are not adequate. While this list is not exhaustive, we think it is a good starting point to address the issues with Hudson's production. We hope that Hudson will take this opportunity to start producing responsive documents as required by the Federal Rules without Court intervention.

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For our part, as explained below, we will continue to produce on a rolling basis documents that are reasonably requested by Hudson.

RUSH'S REQUESTS FOR PRODUCTION

Rush's Request for Production No. 3 seeks all "documents and things concerning correspondence between or among past or present officers, directors, employees, and/or agents" of Hudson concerning the prosecution of the patents-in-suit. This request is particularly relevant because it appears as though the named inventor, Timothy B. Haines, may have worked for defendant Zimmer for a time. Hudson has not produced a single internal document responsive to this request, despite representing in its Response to Rush's Request for Production that responsive documents will be produced. We ask that Hudson immediately disclose these documents.

Many of Rush's Requests pertain to the inventions claimed in the patents-in-suit. Hudson has not produced any internal documents related to the development of its purported invention. Merely photocopying documents from the Patent Office is insufficient to meet Hudson's discovery obligations because they do not describe the actual development of the purported invention. Rush Requests Nos. 8-17, 47, 48, and 93, for example, relate generally to conception, reduction to practice, written description, disclosure, testing, development, use, and/or offers for sale of Hudson's claimed inventions. Documents responsive to these Requests are likely in Hudson's sole control, yet Hudson has not produced a single internal document relating to these Requests. We request immediate disclosure of these documents.

Rush's Requests Nos. 21-23, 50, 61, 94, and 95 relate generally to assignment, ownership, and licensing of the Hudson's relevant patents and surgical techniques. Hudson's production of the Patent Assignment information sheet (H003473 – H003477) demonstrates that the patents-in-suit were the subject of an agreement with First Union National Bank and/or Othy, Inc. Communications with First Union and/or Othy, Inc. concerning this arrangement cannot be subject to a claim of attorney-client privilege or work product immunity and should have been produced (along with many other relevant documents, presumably). Hudson, however, has not disclosed any non-public documents concerning this agreement. Hudson itself has put these documents squarely at issue by claiming in its Rule 26 disclosures that two of the factors at issue in damage computation are "[w]hether or not Hudson Surgical has an established a royalty for the patented invention, for example, by granting other licenses at that royalty" and "[w]hether or not Hudson Surgical has a policy of licensing or not licensing the patents." They are also relevant to the issues of standing and inventorship. We request immediate disclosure of any documents relating to this agreement, and all other documents relating to Hudson's ownership, licensing, or assignment of the patents, inventions, and techniques involved in this suit.

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Rush's Requests Nos. 32, 33, 35-37, and 64 relate to regulatory submissions, testing, and communications. Hudson has not produced a single document relating to regulatory approval for any Hudson product or technique, even though no communication with or submission to any regulatory agency would be shielded by privilege. We request immediate disclosure of these documents.

Rush's Requests Nos. 38-42 relate to Hudson's corporate structure and policies, including but not limited to document retention policies. Although this information is likely in the sole control of Hudson, Hudson has not disclosed a single document relating to its structure or policies. Furthermore, Hudson has put its internal policies squarely at issue by claiming in its Rule 26 disclosure that one factor at issue in damage computation is "[w]hether or not Hudson Surgical has a policy of licensing or not licensing the patents." We request immediate disclosure of any such documents.

Rush's Requests Nos. 45 and 47 relate generally to the job titles, names, and duties of certain individuals, many of whom are Hudson employees. Several of these Hudson employees were specifically identified by Hudson in its initial Rule 26 disclosures. The names, duties, and titles of these individuals could easily have been disclosed, and Hudson's delay in producing this readily-available information hinders the progress of discovery. Rush requests immediate production of this information.

Rush's Request No. 52 involves other charges of infringement by Hudson. Any communications with or charges against an alleged infringer are clearly not shielded by privilege. Furthermore, documents responsive to this Request should be readily available to Hudson and its counsel. Rush requests that Hudson either immediately disclose any such documents or warrant in writing that no other charges of infringement have been made.

Hudson objects to Rush's Request No. 53 because the request is "premature." Rush requests written clarification specifically as to whether any testing has been conducted by Hudson as described in this Request. If any such testing has been conducted, Rush requests that Hudson immediately disclose the results of any such testing.

Rush's Requests Nos. 55 and 56 relate to notice to defendants in this suit. Hudson's claim that Request No. 55 seeks privileged information is particularly puzzling and overbroad, as no privilege exists to shield communications between Hudson and the defendants in this suit. If Hudson cannot produce any documents responsive to these requests, Rush invites Hudson to concede that Hudson provided no notice to Rush regarding the patents-in-suit before the filing of this case.

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Rush's Requests Nos. 60-62, 64, 66, 74, and 94 each generally encompass agreements, correspondence, and communications between Plaintiff and third parties relating to techniques at issue in this case. Any such agreements, correspondence, or communications would not be shielded by privilege and should be produced immediately. We note that in his resume, Mr. Haines stated that at Hudson he was a consultant for Othy and a musculoskeletal transplant foundation, and some of this work might have been related to knee replacements. We request that you provide the agreements with these third parties on any subject, and all documents relating to knee replacements.

Rush's Requests Nos. 26, 66-73 and 75 generally relate to sales, pricing and marketing of Hudson's products and techniques. In Mr. Haines' resume, he claims to have developed and marketed products while at Hudson, and it is likely that the products developed would include knee replacement implants and instrumentation. Hudson, however, has not produced any documents relating to these products in response to Rush's requests.

Rush's Requests 76-78 relate to basic information concerning marking, packaging, and instructions. In his resume, Mr. Haines claims to have "developed instrumentation and prosthesis designs from conceptualization through finalization" while at Hudson. It is therefore likely that documents responsive to these requests exist, but as of yet none have been produced. Please produce these documents immediately.

RUSH'S INTERROGATORIES

In addition, many of Hudson's objections and responses to Rush's Interrogatories are either improper or deficient. Hudson's Objection No. 3 could be read as though Hudson is suggesting that it need not produce and/or identify the most relevant documents in response to Rush's discovery requests. Rush requests that Hudson amend its objection to clarify that Hudson will certainly identify and produce the documents that Hudson feels are most relevant.

In objection No. 6, Hudson purports to restrict its responses to not provide, where requested, a summary of each identified person's knowledge. Hudson provides no basis for such a restriction, and indeed none is present in the Federal Rules. Rush requests that this objection be lifted and that Hudson provide, where requested, a summary of each identified person's knowledge for each respective interrogatory.

In objection No. 10, Hudson provides that it would limit its response subject to entry of a protective order. Please confirm that, in fact, Hudson has not limited any response based on any claim of a trade secret, or proprietary or confidential information.

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In objection No. 12, Hudson states an objection as to third party confidential information. However, in its actual responses it does not identify specific documents and/or information that are not being disclosed based on that objection, if any. If no documents and/or information have been withheld on this basis, please confirm that fact. If documents and/or information have been withheld, please identify the type of document and/or information, the location of the document and/or information, the third party involved, and the steps that Hudson has taken to resolve any third party concerns.

In response to Interrogatory No. 1, Hudson states that it may rely on an expert in the claim construction process. We request that Hudson identify that expert immediately and disclose his opinions so that Rush has the opportunity to refute any opinions of the expert and take his or her deposition. This information is required now because the scheduling for the claim construction briefing period is in a couple months (before other expert discovery) and the time period for responding is not expansive.

For Interrogatory No. 4, please identify and describe the contents of the written offer and all documents surrounding it.

Hudson's response to Interrogatory No. 6 is totally inadequate. Rush sought information relating to the conception, reduction to practice, diligence, and disclosure of the purported invention. Your response is not contingent on anything from Rush or Zimmer; information on Hudson's claimed invention is exclusively in the hands of Hudson, so your objection based on Rush's discovery responses is wholly unwarranted. Your entire substantive response is the bare allegation that the subject matter of the asserted claims was conceived and reduced to practice prior to September 30, 1996. Your identification of documents is limited to publicly available patent documents. In other words, Hudson does not provide any substantive information in response to this interrogatory or identify any non-public document regarding the purported development of the subject matter of the asserted claims. We request that you supplement this response immediately.

Hudson's response to Interrogatory No. 7 is similarly inadequate. It fails to provide any information regarding the assignment of the security interest in the patents-in-suit to a third party bank by Othy, Inc. and its subsidiaries, which was a transfer of rights relating to the patent. Information surrounding another company's claim to rights in the patents-in-suit is highly relevant to the issues of this case, including for the issues of inventorship and standing. Whether you assert that the transfer was proper or not has no bearing on the relevance of this transfer. We request that you supplement this response immediately.

Hudson's response to Interrogatory No. 11, which seeks information regarding a reasonable royalty rate, is evasive and non-responsive. Your response repeatedly identifies factors that

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include information in the hands of Hudson, yet you fail to provide the actual information. For example, Hudson identifies the factor "[w]hether Hudson has a policy of licensing or not licensing the patents-in-suit." Hudson is the party with that information, yet Hudson does not state whether Hudson has a policy of licensing, and if so what it that policy entails. Rush's interrogatory sought actual information, not a list of potential factors that does not provide any actual information. We request that you supplement this response immediately.

Hudson's response to Interrogatory No. 15 is similarly evasive. Rush specifically asked whether it was Hudson's position that the claims asserted were for a "medical activity" and whether Rush and Rush System for Health were each a "related health care entity." Hudson did not respond to this inquiry. Further, Hudson only makes a bare assertion regarding effective filing dates, without providing the information to support that assertion. Specifically, for each claim of the '541 patent that Hudson is asserting, Hudson should provide an identification of where in the specification it finds support for each claim element and identify the effective filing date of that portion of the specification. We request that you supplement this response immediately.

RUSH'S PRODUCTION

We now turn to the issues raised in your letter regarding Hudson's discovery demands. As an initial matter, we find your demands as a whole to be quite burdensome, especially in relation to the liability restrictions present in this action. Specifically, despite repeated requests, Hudson has not demonstrated any reasonable basis for asserting liability against Rush for any time before initiation of this lawsuit. It is quite clear that Hudson has no evidence of direct infringement of the '272 patent by Rush for any time period, not the least of which is the fact that any apparatus used in a Rush surgery has not been shown to have "cutting guides positionable in opposing relation along the sides of the tibia." Your claim chart for the '272 patent, which leaves this required element of the patent claim "not shown," only establishes that there is no infringement. This essential element is "not shown" because it does not exist in any known apparatus used in a knee replacement surgery at Rush. Furthermore, Rush cannot be liable for indirect infringement of the '272 patent because, as Hudson admits in its interrogatory response, there is no evidence that Rush was aware of that patent prior to the filing date of this action. Because Hudson has not shown a reasonable basis for asserting infringement prior to the initiation of this action, discovery for that time period, especially where it is onerous and burdensome on Rush, should be at the least severely limited.

We are investigating your request regarding preferences cards listing MIS Tibial Cutting Jigs and Quad Sparing Femoral Trays. We have already provided you with the documents revealed thus far in our investigation concerning the chain of custody of those instruments (RUMC0002187 - RUMC0002654). This document provides the information you seek regarding the availability of these trays in the operating room for knee replacement surgeries. While we do not think we were

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required to produce all of these documents based on the temporal liability limitations mentioned above, we produced all such information that is available on Rush's current software platform, and it would be a burden to provide additional information that may or may not exist on legacy systems.

As to your inquiry regarding agreements between Zimmer and Rush, we have produced all agreements between Zimmer and Rush relating to the sale and/or use of knee replacement implants and/or instruments of which we are currently aware.

As to your inquiry regarding the usage and purchases of Zimmer products, we have provided you with that data from 2006 onward (see RUMC0002655 - RUMC0004958; RUMC0001648 - RUMC0001927).

Our investigation has not revealed any information regarding training programs presented by Rush regarding quad-sparing techniques or instrumentation. Your letter states that you are aware of "numerous such programs." To aid our investigation, please provide us with the names, dates, and any other information you possess relating to any training programs administered by Rush (not by Midwest Orthopaedics or Zimmer).

Our investigation has thus far not revealed any additional contracts or types of agreements between physicians and RUMC. As you can see on the standard Request for Clinical Privileges form (RUMC0001965 - RUMC0001967; RUMC0001990 - RUMC0002015), the surgical privileges granted to doctors on this form are not broken down in specific enough detail to identify doctors performing quad-sparing knee replacement surgery. Rush does not have its agreements with physicians in an easily searchable manner. If you identify specific doctors that you contend are relevant, we would consider looking for their agreements. However, as stated before, the privilege agreements are not relevant to this action because they do not differentiate between the type of knee surgery, and so one could not tell from such agreements whether there is infringement or not.

Your letter also inquires into documents relating to the actual techniques and devices used during knee replacement surgeries. As we have indicated, Rush does not have documents that provide this information. We have produced, as a sample, surgeon's clinical notes for one surgery completed by Dr. Berger (RUMC0002016-20), along with a patient billing summary (RUMC0001551 - RUMC0001552), a surgical history report (RUMC0001546 - RUMC0001550), and Dr. Berger's preference card (RUMC0001543 - RUMC0001545) for that same surgery.

As an initial manner, the production of these documents for just this one surgery imposed a substantial burden on Rush. These documents are not maintained together in one area, but are

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rather kept in different files in different areas that must be searched individually by different criteria. Further, they required extensive redaction of information to comply with federal patient-confidentiality requirements under HIPAA. As a result, it would not be possible for Rush to provide each of these documents for each of the thousands of surgeries completed at Rush over the last several years because the hours required for such a production would be truly enormous. We note that the prevention of this burden was a reason why Congress passed 287(c) to limit patent lawsuits against medical care providers for surgical techniques.

Furthermore, as you can see from the preference card, several instrument trays were requested for the surgery. The preference card notes that a subvastus approach was planned. The surgical notes demonstrate, however, that a mini-midvastus medial athrotomy was actually performed. The surgical notes do not indicate the instruments actually used to perform this approach. It is unclear which approach, if any, Hudson is asserting infringement against – the category of "quad sparing" may not be sufficient. We therefore request that you identify which approach to surgery you contend is an infringement. Overall, these documents do not bear sufficient relevance to require the inordinate burden that would be required to produce them, especially given the tenuous nature of Hudson's claim of liability for the time before initiation of this lawsuit and the fact that the surgeons themselves are likely the best source of information relating to how they perform their surgeries.

You asked in your letter that we identify other sources of information sought by Hudson. We do not understand your purported confusion on this matter, especially given that Hudson has produced documents and is seeking them from other sources such as Midwest Orthopaedics and Zimmer which are clearly "other sources" (see, e.g., H005855 - H005856; H005925- H005927; H005944 - H005948; H007662 - H007672). We also refer you to our supplemental Rule 26(a)(1) statement, which identifies specific persons with information on different topics.

As to Rush's interrogatory responses to Nos. 2-4, we think this issue is newly raised. Originally, you requested that we supplement interrogatory No. 1 to identify persons with knowledge of certain subjects. In lieu, we provided a supplemental Rule 26(a)(1) disclosure that identified additional persons. We further note that we have now produced documents that provide the information requested in these interrogatories. Of course, we will also supplement our responses in a timely manner where appropriate.

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We hope that this has resolved the issues raised in your letter of July 18, 2008. We also reiterate our request that Hudson produce documents responsive to Rush's requests.

Sincerely,

Thomas J. Maas/CLG

Thomas J. Maas

TJM:clg